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Fortier

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[54] **TROCAR WITH REMOVABLE, REPLACEABLE TIP**

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[73] Assignee: **NeoSurg Technologies**, Houston, Tex.

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[51] **Int. Cl.**[7] **A61B 17/34**

[52] **U.S. Cl.** **606/185**; 604/164.06

[58] **Field of Search** 606/185; 604/164, 604/164.01, 164.06; 30/340, 329; 81/489; 16/422, 426, 427

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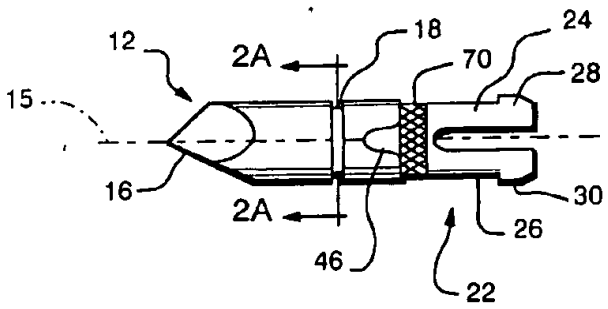
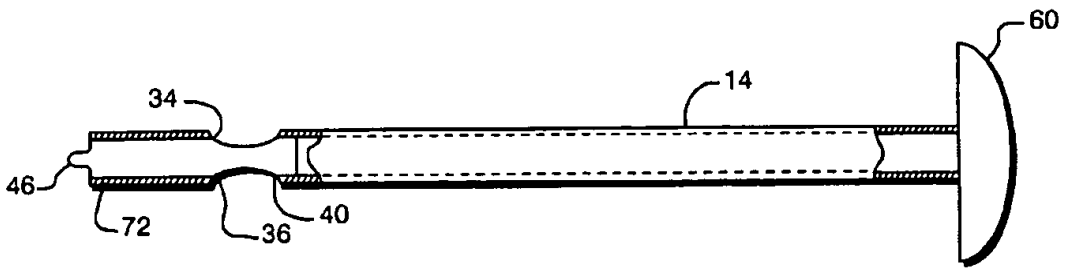
[57] **ABSTRACT**

A trocar obturator having a removable replaceable tip includes an obturator tip having a sharpened distal end and a first engagement device on its proximal end; an obturator shaft having a second engagement device on its distal end for lockingly engaging the first engagement device and securing the tip and shaft together; one of the engagement devices borne by one of the tips and shafts includes a flexible member biased to engage the engagement devices; there are access means for flexing the flexible member against its bias to disengage the engagement devices to release the tip and shaft.

28 Claims, 7 Drawing Sheets





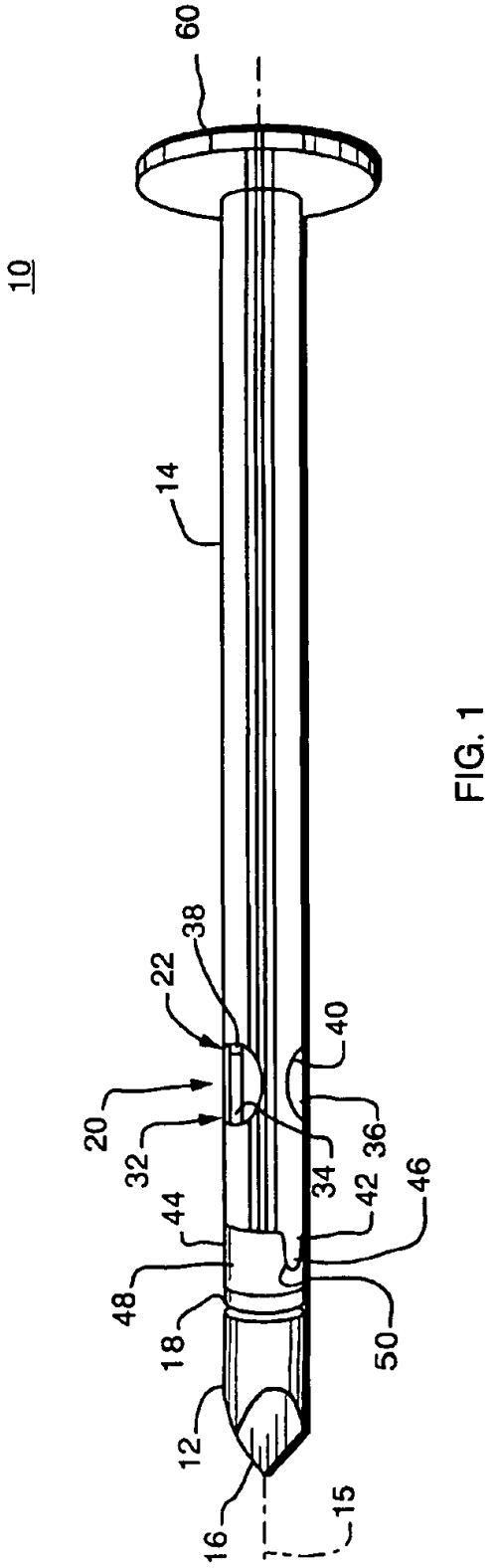


FIG. 1

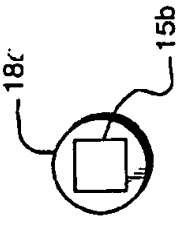


FIG. 2C

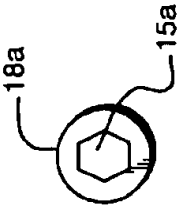


FIG. 2B

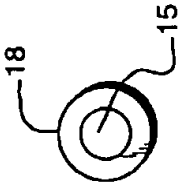


FIG. 2A

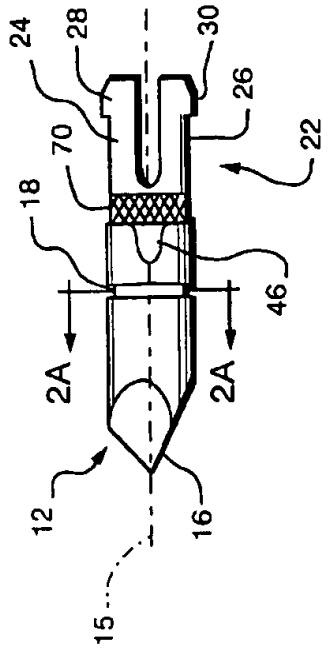


FIG. 2

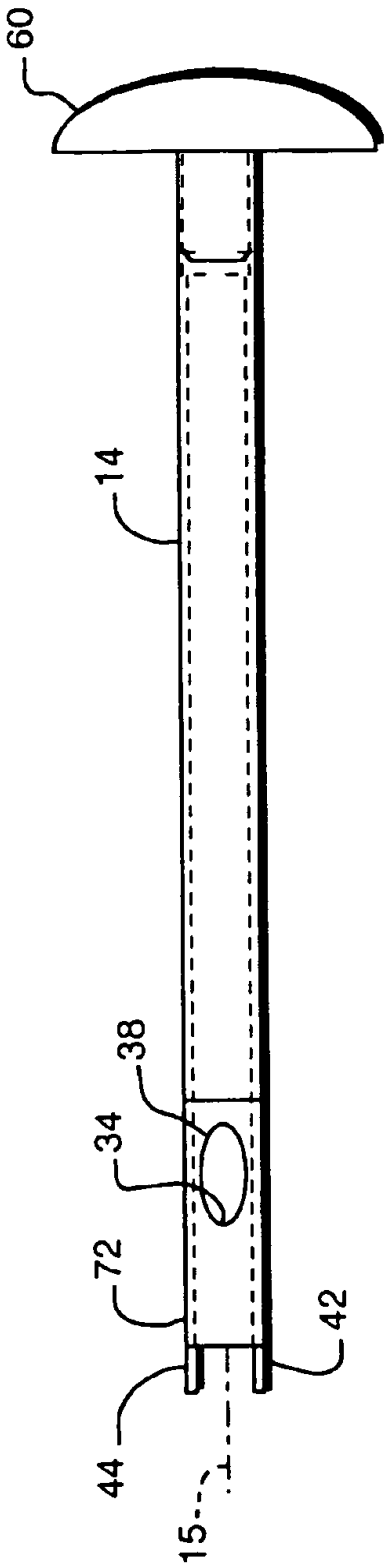


FIG. 3

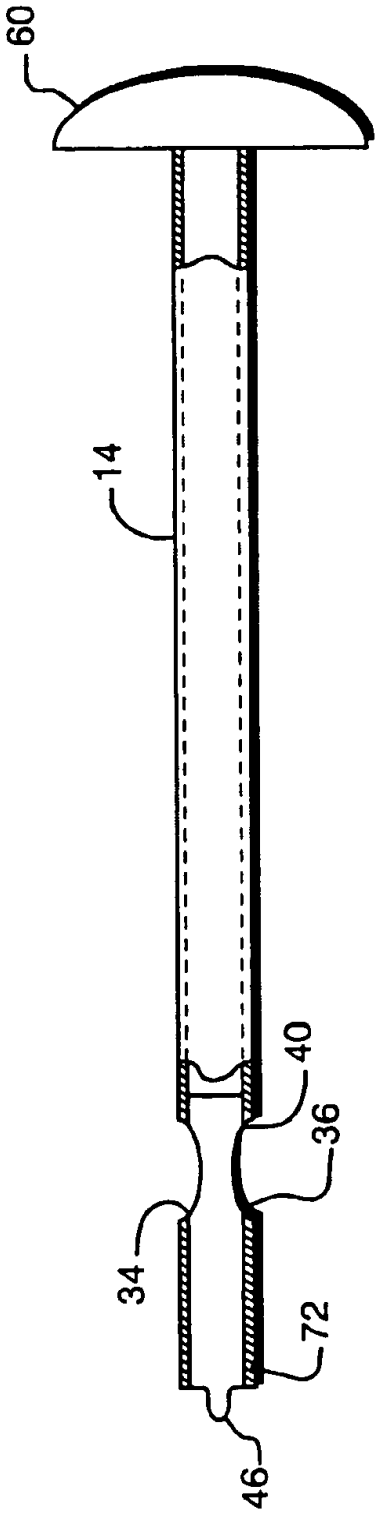


FIG. 4

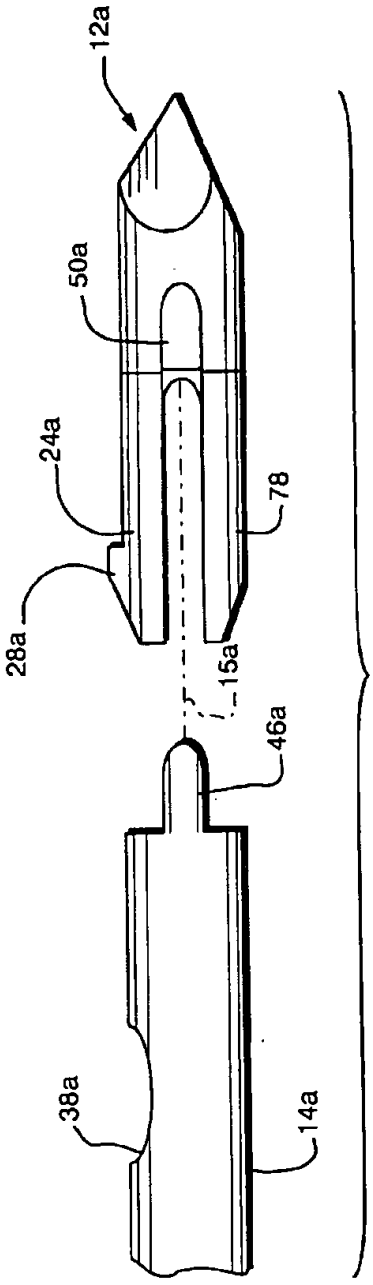


FIG. 5

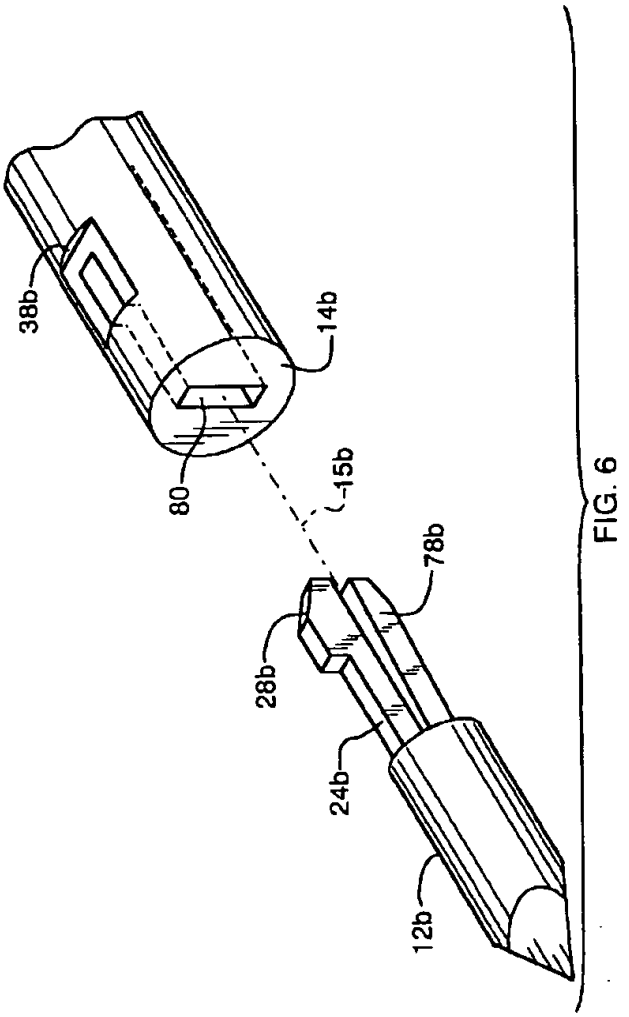
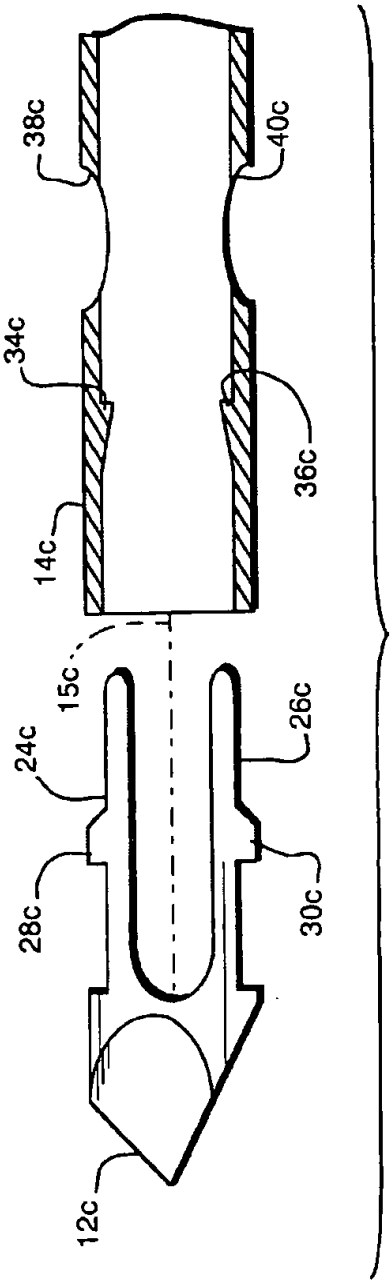


FIG. 6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40c
34c
36c
14c
15c
24c
26c
28c
30c
12c

FIG. 7

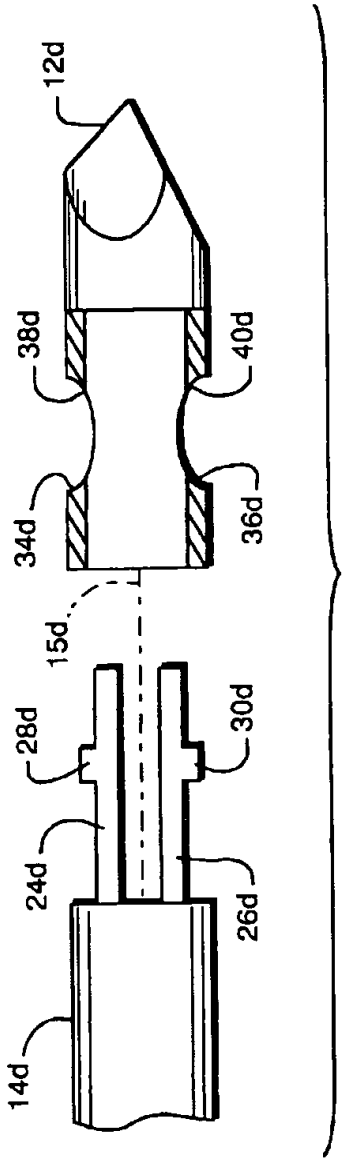

12d
38d
40d
34d
36d
15d
28d
30d
24d
26d
14d

FIG. 8

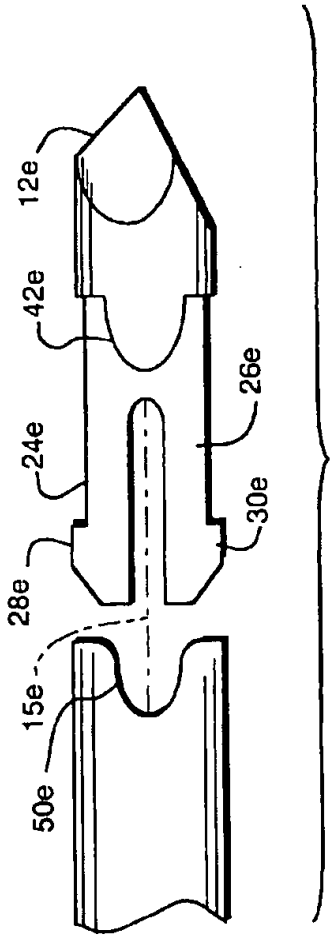
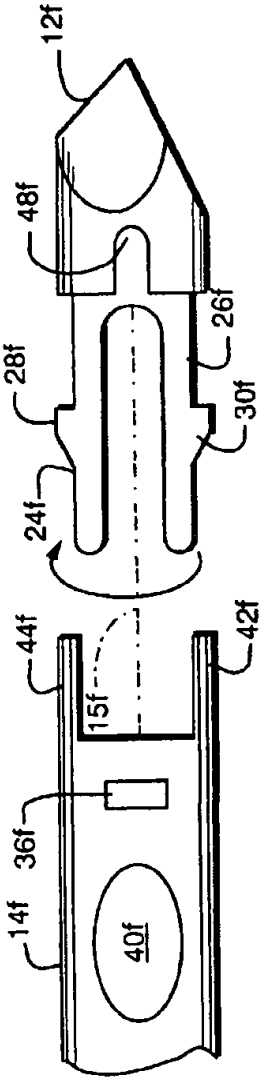

12e
42e
26e
24e
30e
28e
15e
50e

FIG. 9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48f
26f
28f
30f
24f
44f
42f
15f
36f
14f
40f

FIG. 10

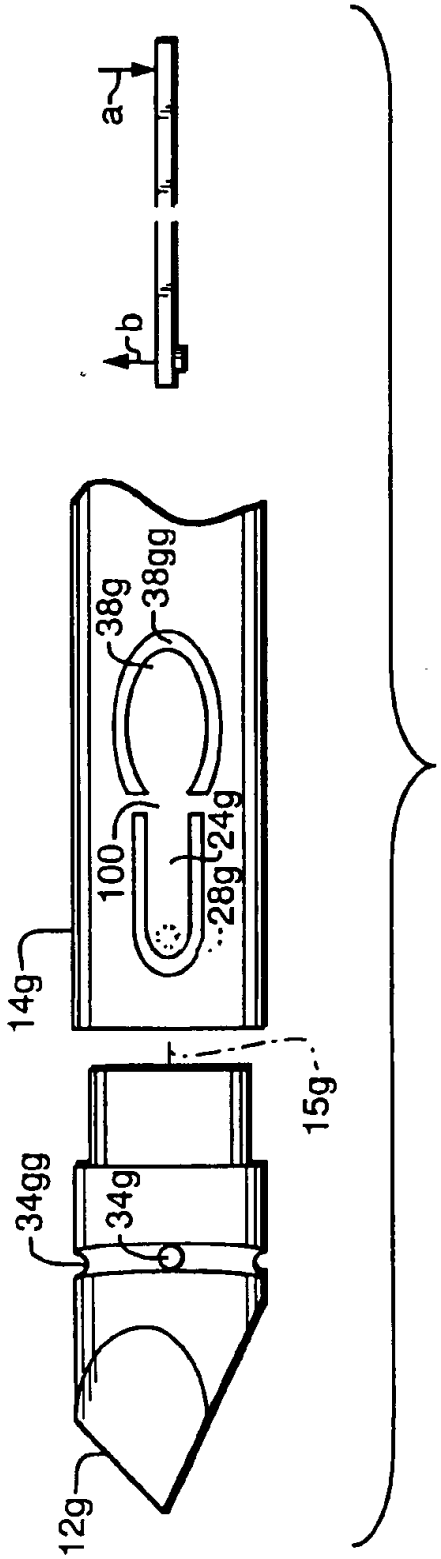

FIG. 11

TROCAR WITH REMOVABLE, REPLACEABLE TIP

FIELD OF INVENTION

This invention relates to an improved obturator having a removable, replaceable tip and more particularly to such a removable, replaceable tip which flexibly engages and releases the obturator tip and shaft.

BACKGROUND OF INVENTION

Conventional trocars use an obturator with a sharp metal tip to penetrate a body cavity in surgical procedures. After each use the obturator must be sterilized and eventually the tip dulls and must be re-sharpened by machining. These obturators are expensive and adding to their effective cost is the cost of sharpening, sterilizing and the loss of use during those procedures. Some trocars including housing, handle, cannula and obturator are made to be disposable: they are made to be used once and discarded with no need for resharpening or sterilizing but their initial cost is quite high. Some trocar obturators are made with a removable metal tip so that tips of different cutting configurations can be used by simple removal and replacement of them from the obturator shaft. But these tips, too, are expensive and must be regularly sterilized and periodically re-sharpened.

SUMMARY OF INVENTION: I

It is therefore an object of this invention to provide an improved obturator having a removable, replaceable tip.

It is a further object of this invention to provide such an obturator which is disposable after a single use.

It is a further object of this invention to provide such an obturator which is inexpensive and easy to install and removal.

It is a further object of this invention to provide such an obturator which is always at peak sharpness and sterile and involves no re-sharpening or sterilization.

It is a further object of this invention to provide such an obturator which sensibly indicates when the tip is seated in the shaft.

The invention results from the realization that a truly cost effective, disposable obturator can be achieved with a separable tip and shaft which have means for properly orienting them and releasably engaging and disengaging them using a flexible member on one bearing a detent which engages with a stop on the other under the bias of the flexible member to secure the tip and shaft which can easily be disengaged by moving the flexible member against its bias to release the detent from the stop and free the tip from the shaft.

This invention features a trocar obturator having a removable replaceable tip including an obturator tip having a sharpened distal end and a first engagement device on its proximal end. There is an obturator shaft having a second engagement device on its distal end for lockingly engaging the first engagement device and securing the tip and shaft together. One of the engagement devices borne by one of the tips and shafts includes a flexible member biased to engage the engagement devices. There are access means for flexing the flexible member against its bias to disengage the engagement devices to release the tip and shaft.

In a preferred embodiment there may be alignment means for defining orientation of the tip and shaft. The alignment means may include a salient portion on one of the tip and shaft and a mating recess on the other. One of the engagement devices on one of the tips and shafts may be asymmetrical in shape and the alignment means may include a conforming guide recess on the other of the tip and shaft for orienting the tip and shaft. The tip may include a circumferential removal groove. The groove may have a circular shape or a polygonal shape such as a square. There may be an indicator surface on one of the tips and shafts and a cover member on the other for covering the indicator surface when the tip and shaft are engaged. The indicator surface may include a contrasting color region. The flexible member may snap the engagement devices together to make an audible indication that the tip and shaft are secured. The tip may be made of plastic such as polycarbonate, ABS, or polysulfone. One of the engagement devices may include at least one flexible leg with a detent and the other engagement device may include a stop means for engaging the detent. The flexible leg may be included on the first engagement device on the tip and the stop means may be on the second engagement device on the shaft. Or the flexible leg may be on the second engagement device on the shaft and the stop means may be on the first engagement device on the tip. The stop means may include a stop recess for receiving the detent or it may include a stop shoulder for abutting the detent. The access means may include a port for manipulating the flexible leg and it may be on the shaft or the tip. The access means may include a resilient tab interconnected with the flexible leg for flexing the leg against its bias to release the tip and shaft. The stop means may include a peripheral slot.

The invention also features a trocar obturator having a removable replaceable tip including an obturator tip having a sharpened distal end and a flexible leg extending from the proximal end and having a detent thereon. An obturator shaft has a stop means for engaging the detent. The flexible leg is biased to engage the detent and stop means to secure the tip and shaft. An access port is provided for moving the leg to overcome its bias, disengage the detent and stop means and release the tip and shaft.

In a preferred embodiment the stop means may include a stop recess for receiving the detent or a stop shoulder for abutting the detent. The access port may be in the shaft and the stop recess may form a part of the port.

This invention also features a trocar obturator having a removable replaceable tip including an obturator tip having a sharpened distal end, an obturator shaft, and engaging means for releasably securing the tip and shaft including a flexible leg having a detent on one of the tip and shaft and stop means on the other for engaging the detent, the flexible leg being biased to engage the detent and step means and secure the tip and shaft. There are access means for moving the leg to overcome its bias, disengage the detent and stop means and release the tip and shaft.

In a preferred embodiment the flexible leg may be on the tip and the stop means may be on the shaft, or the flexible leg may be on the shaft and the stop means on the tip.

DISCLOSURE OF PREFERRED EMBODIMENT

Other objects, features and advantages will occur to those skilled in the art from the following description of a preferred embodiment and the accompanying drawings, in which:

FIG. 1 is a three-dimensional view of a trocar obturator including a removable replaceable tip according to this invention;

FIG. 2 is an enlarged detail view of the obturator tip of FIG. 1;

FIG. 2A is a cross-sectional view taken along lines 2A—2A of FIG. 2 showing a groove which has a circular shape;

FIG. 2B is a view similar to FIG. 2A in which the groove has a polygonal shape;

FIG. 2C is a view similar to FIGS. 2A and 2B wherein the groove has a square shape;

FIG. 3 is a enlarged detailed plan view of the obturator shaft of FIG. 1;

FIG. 4 is an enlarged detailed elevational view of the obturator shaft of FIG. 1;

FIG. 5 is a view similar to FIG. 2 wherein there is but one flexible leg, one detent and one access hole;

FIG. 6 is a three-dimensional view of the tip of FIG. 5 showing an asymmetric slot in the shaft for definitively orienting the tip and shaft assembly;

FIG. 7 is an enlarged detailed side elevational view of another embodiment of the removable replaceable tip according to this invention employing two flexible legs with detents for mating with internal stop shoulders on the shaft;

FIG. 8 is a view similar to FIG. 7 of another embodiment of the removable replaceable tip according to this invention in which flexible legs with detents are on the shaft and the tip contains access ports a portion of which function as stop recesses;

FIG. 9 is a view similar to FIG. 2 in which the alignment means have the salient portion on the tip and the mating recess portion on the shaft;

FIG. 10 is a view similar to FIG. 9 of another embodiment of the removable replaceable tip of this invention in which the stop means includes a stop recess separate from the access port; and

FIG. 11 is a view similar to FIG. 9 of another embodiment of the removable replaceable tip of this invention in which the detent is borne by a flexible leg interconnected with a resilient actuator tab on the shaft and the stop recess is a circumferential groove on the tip.

There is shown in FIG. 1 a trocar obturator **10** according to this invention including an obturator tip **12** and shaft **14** with a longitudinal axis **15**. Tip **12** includes a sharpened distal end **16** and a removal groove **18** for receiving, for example, forceps, to remove tip **12** from shaft **14**. Referring to FIGS. **1**, **2**, **3** and **4**, it can be seen that there are engagement means **20** which include an engagement device **22** on tip **12** comprised of a pair of flexible legs **24**, **26** having detents **28** and **30**. There is also an engagement device **32** on shaft **14** which includes the stop means formed by the stop recesses **34** and **36** that form a part of the oval ports **38** and **40** that constitute the access means by which the fingers of a surgeon can reach and squeeze legs **24** and **26** to move detents **28** and **30** out of contact with stop recesses **34** and **36** in order to release tip **12** from shaft **14**. Flexible legs **24** and **26** have a sufficient bias to maintain detents **28** and **30** in contact with stop recesses **34** and **36** and to provide a snap fit which makes a clicking noise when tip **12** is inserted and seated properly in shaft **14** so the surgeon has an audible confirmation that the shaft and tip are locked together. In order to compel the tip **12** to be inserted in shaft **14** so that legs **24** and **26** align with access ports **38** and **40**, alignment means **42** consisting of tabs **44** and **46** extending saliently from shaft **14** and recesses **48** and **50** on tip **12** are provided. A handle or hub **60** is provided on the proximal end of shaft **14** to be used to apply pressure to push the sharp end **16** of tip **12** through the body tissue. Shaft **14** is hollow, at least at its distal end to provide for access ports **38** and **40** and permit the legs **24** and **26** of tip **12** to be inserted. To provide for strength, sharp cutting edges and the snap fitting action and sound, the trocar may be made of a metal or of a plastic such as of polycarbonate, ABS, polysulfone.

Visual indicia may be provided in the form of a contrasting color or texture or pattern **70**, FIG. **2**, which will be covered by cover portion **72**, FIGS. **3** and **4**, of shaft **14** when tip **12** is properly secured in shaft **14** so the surgeon will have another confirmation that the obturator is properly and safely assembled.

In operation, tip **12** is inserted in shaft **14** by simply pressing the ends of legs **24** and **26** against the cover portion **72** of shaft **14**. Legs **24** and **26**, being flexible, will flex inward so that detents **28** and **30** will pass under the cover portion and will spring out in ports **38** and **40** making a clicking sound when detents **28** and **30** spring into position at stop recesses **34** and **36**. At this point the color band **70** will no longer be visible as it is hidden by the cover portion **72**. When the surgical procedure is finished and it is desired to remove tip **12**, tip **12** can be gripped by fingers or by a tool such as a forcep which would engage with groove **18** and then the surgeon may place a thumb and forefinger over access ports **38** and **40**, depressing legs **24** and **26** so that detents **28** and **30** disengage from stop recesses **34** and **36**.

Groove **18** has a circular shape or circumference as shown in FIG. 2A, but it may as well have a polygonal shape such as hexagonal shape **18***a*, FIG. 2B, or square shape **18***b*, FIG. 2C, to better receive a wrench-like conformation or forceps.

Although in FIGS. **1–4** tip **12** is shown with a pair of flexible legs with detents and a pair of access ports, as well as a pair of alignment tabs these are not necessary limitations of the invention. For as shown in FIG. **5**, tip **12***a* may include a single recess **44***a* to receive a single salient tab **46***a*. Obturator tip **12***a* has but a single flexible leg **24***a* with detent **28***a* accessible through a single port **38***a*. All tabs **46** and recesses **50***a* used for alignment purposes may be eliminated, for example, and replaced by an alignment slot **80**, FIG. **6**, which is asymmetrical and conformed to receive the asymmetrical shaped legs **24***b* and **78***b* so that the tip **12***b* is automatically properly aligned with shaft **14***b*. Element **78** which may take any particular form including a shape similar to leg **24***a* may be provided to keep tip **12***a* trued up and properly oriented in shaft **14***a*.

While the stop means thus far have been shown as a part of access ports **38** and **40**, this is not a necessary limitation of the invention as they may in fact be constructed as internal stop shoulders **34***c*, **36***c*, FIG. **7**, which engage detents **28***c* and **30***c* on legs **24***c* and **26***c*.

In addition, although thus far the flexible leg or legs and detents have been shown as a part of the tip and the access ports and stop means have been shown as a part of the shaft, this is not a necessary limitation of the invention as the converse is also contemplated by this invention as shown in FIG. **8**, where tip **12***d* includes access ports **38***d* and **40***d* having stop recesses **34***d* and **36***d* while shaft **14***d* contains flexible legs **24***d* and **26***d* having detents **28***d* and **30***d*. In addition, although the alignment means have been shown with the salient tab on the shaft and the recess on the tip, this is not a necessary limitation of the invention, for as shown in FIG. **9** one or more salient tabs **42***e* may be provided on tip **12***e* to self-center and nest in one or more recesses **50***e*.

The access port or ports for reaching flexible legs and compressing them inwardly against their bias may not provide a recessed stop as a part of its configuration. Rather, as shown in FIG. **10**, where tip **12***f* has been rotated 90° with respect to shaft **14***f* the stop recess **34**, **36***f* has been independently provided to engage detent **28***f* on leg **24***f* and a similar stop recess, not shown, is provided on the opposite side of shaft **14***f*. In FIG. **10**, for proper rotational orientation of the tip **12***f* and shaft **14***f*, tip **12***f* must be rotated so that

leg **24***f* comes out of the paper and leg **26***f* rotates into the paper about the central longitudinal axis **15** so that detent **24** fits into stop recess **36***f*.

Although the access means has been shown as one or more ports, this is not a necessary limitation of the invention. For example, as shown in FIG. **11**, flexible leg **24***g* having internally extending detent **28***g* is flexibly interconnected at junction **100**, FIG. **11**, with access actuator tab **38***g* in opening **38***gg* so that a downward pressure on tab **38***g* rocks leg **24***g* upwardly, lifting detent **28***g* out of stop recess hole **34***g*. A similar construction may be duplicated on the opposite side of tip **12***g* and shaft **14***g*. Hole **34***g* may be replaced by a circumferential slot **34***gg* so that orientation is not a problem as detent **28***g* and a complementary one on the other side of shaft **14***g* can engage anywhere along groove **34***gg*.

Although specific features of this invention are shown in some drawings and not others, this is for convenience only as each feature may be combined with any or all of the other features in accordance with the invention.

Other embodiments will occur to those skilled in the art and are within the following claims:

What is claimed is:

1. An obturator having a removable replaceable tip comprising:

an obturator tip having a sharpened distal end and a first engagement device on its proximal end;

an easily sterilizable tubular, hollow-bodied obturator shaft having a second engagement device on its distal end for lockingly engaging said first engagement device and securing said tip and shaft together;

one of said engagement devices borne by one of said tip and shaft including a flexible member biased to engage the other said engagement device; and

toolless access means for enabling the use to directly access and flex, toward the radial center of said shaft, said flexible member against its bias to disengage said engagement devices to release said tip from said shaft, said toolless access means operatively sized and shaped to receive the user's finger such that the user can disengage said engagement devices without using any tools.

2. The obturator of claim **1** further including alignment means for defining orientation of said tip and shaft.

3. The obturator of claim **2** in which said alignment means includes a salient portion on one of said tips and shafts and a mating recess on the other.

4. The obturator of claim **2** in which one of said engagement devices on one of said tip and shaft is asymmetrical in shape and said alignment means includes a conforming guide recess on the other of said tip and shaft for orienting said tip and shaft.

5. The obturator of claim **1** in which said tip includes a circumferential removal groove.

6. The obturator of claim **5** in which said groove has a circular shape.

7. The obturator of claim **5** in which said groove has a polygonal shape.

8. The obturator of claim **1** further including an indicator surface on one of said tip and shaft and a cover member on the other for covering said indicator surface when said tip and shaft are engaged.

9. The obturator of claim **1** in which said indicator surface includes a contrasting colored region.

10. The obturator of claim **1** in which said flexible member snaps said engagement devices together to make an audible indication that said tip and shaft are secured.

11. The obturator of claim **1** in which said tip is made of plastic.

12. The obturator of claim **11** in which said plastic is from the group consisting of polycarbonate, ABS and polysulfone.

13. The obturator of claim **1** in which one of said engagement devices includes at least one flexible leg with a detent and the other engagement device includes a stop for engaging said detent.

14. The obturator of claim **13** in which said stop means is a stop recess for receiving said detent.

15. The obturator of claim **13** in which said stop means is a stop shoulder for abutting said detent.

16. The obturator of claim **13** in which said access means includes a port which allows for manual manipulation of said flexible leg.

17. The obturator of claim **13** in which said stop means includes a peripheral slot.

18. The obturator of claim **1** in which said flexible leg is included on said first engagement device on said tip and said stop means is on said second engagement device on said shaft.

19. The obturator of claim **1** in which said flexible leg is included on said second engagement device on said shaft and said stop means is on said first engagement device on said tip.

20. The obturator of claim **1** in which said access means is on said shaft.

21. The obturator of claim **1** in which said access means is on said tip.

22. An obturator having a removable, replaceable tip comprising:

an obturator tip having a sharpened distal end and a flexible leg extending from the proximal end and having a detent thereon;

an tubular, hollow bodied obturator shaft having stop means for engagement with said detent, said flexible leg being biased to engage said detent with said stop means to secure said tip and shaft; and

a toolless access port to enable the user to directly access and flex said leg inward toward the radial center of said shaft to overcome its bias, disengage said detent and stop means and release said tip from said shaft.

23. The obturator of claim **22** in which said stop means includes a stop recess for receiving said detent.

24. The obturator of claim **22** in which said stop means includes a stop shoulder for abutting said detent.

25. The obturator of claim **22** in which said access port is in said shaft and said stop recess forms a part of said port.

26. An obturator having a removable, replaceable tip comprising:

an obturator tip having a sharpened distal end;

an tubular, hollow bodied obturator shaft

engaging means for releasably securing said tip and shaft including a flexible leg having a detent on one of said tip and shaft and stop means on the other for engagement with said detent; said flexible leg being biased to engage said detent with said stop means and secure said tip and shaft; and

access means for enabling the user to directly access and move said leg inward toward the radial center of said shaft to overcome its bias, disengage said detent and stop means and release said tip from said shaft.

27. The obturator of claim **26** in which said flexible leg is on said tip and said stop means is on said shaft.

28. The obturator of claim **26** in which said flexible leg is on said shaft and said stop means is on said tip.

* * * * *

US005690663A

United States Patent [19]

Stephens

[11] Patent Number: 5,690,663

[45] Date of Patent: Nov. 25, 1997

[54] **SAFETY TROCAR**

[75] Inventor: **Randy R. Stephens**, Fairfield, Ohio

[73] Assignee: **Ethicon Endo-Surgery Inc.**, Cincinnati, Ohio

[21] Appl. No.: **657,532**

[22] Filed: **Jun. 4, 1996**

Related U.S. Application Data

[63] Continuation of Ser. No. 296,217, Aug. 25, 1994, abandoned.

[51] **Int. Cl.**[6] **A61B 17/34**

[52] **U.S. Cl.** **606/185**; 604/264

[58] **Field of Search** 604/164, 264; 606/1, 167, 171–185

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Primary Examiner—Glenn Dawson

Attorney, Agent, or Firm—Paul A. Coletti

[57] **ABSTRACT**

A safety trocar is provided which includes a spring-loaded shield that shields the cutting tip of the obturator after the obturator penetrates tissue. The distal end of the shield is conical in profile and contains a slot which conforms to the geometry of the cutting tip. The obturator tip contains a knife edge blade which extends the length of the cannula inner diameter. Ideally, the knife is made of an amorphous metal, and may be serrated at its edge. In one embodiment, the knife edge is contacted directly to a portion of the safety shield.

4 Claims, 4 Drawing Sheets

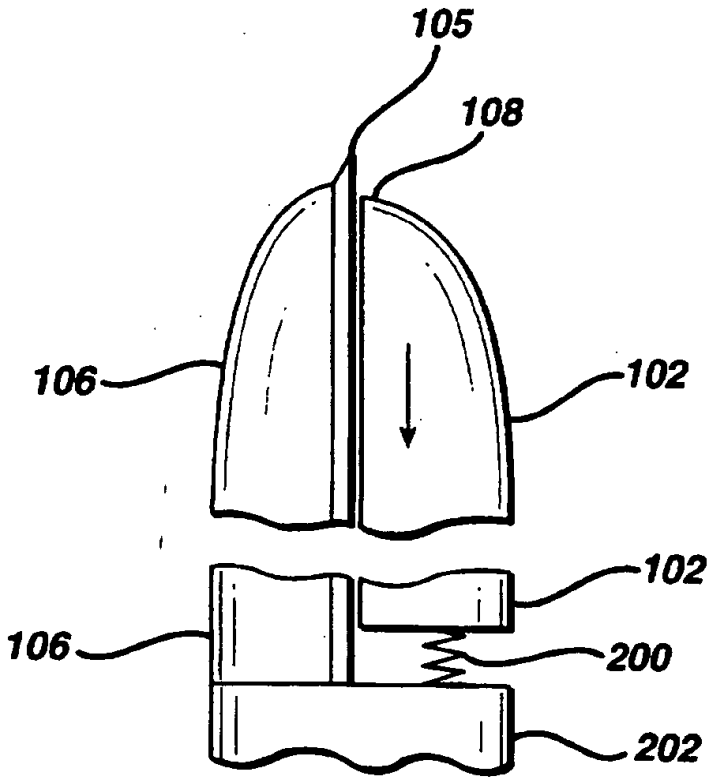


FIG. 1

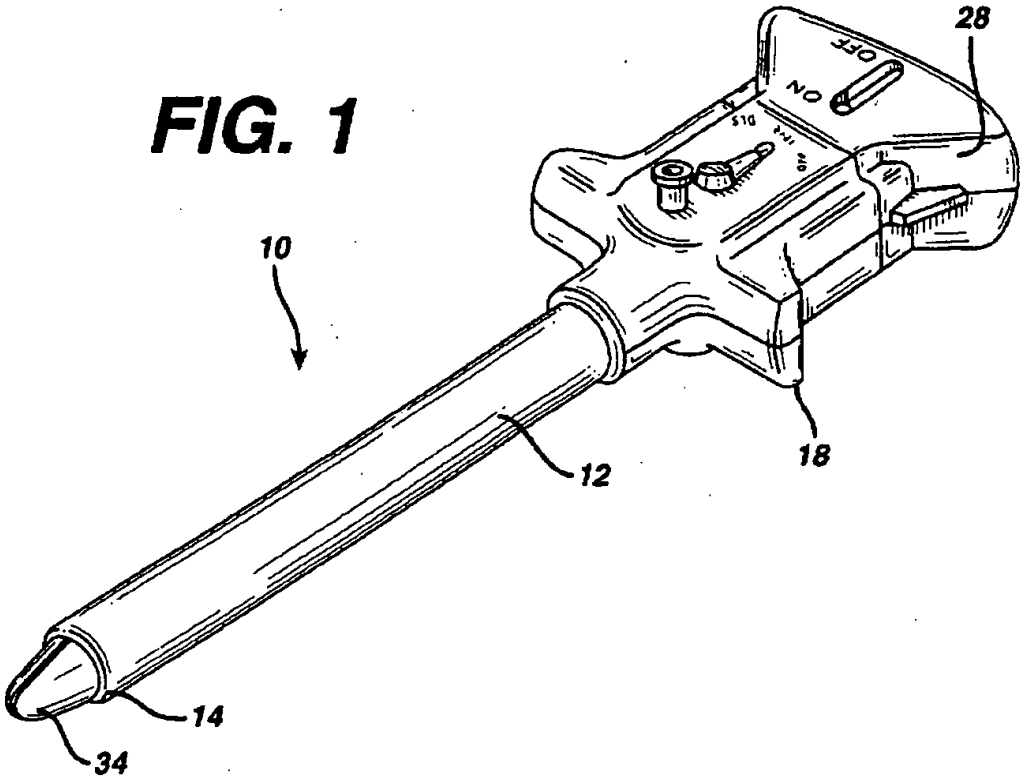


FIG. 2

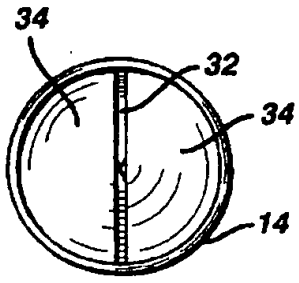


FIG. 3

PRIOR ART

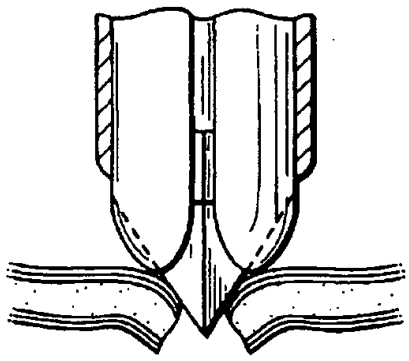


FIG. 4

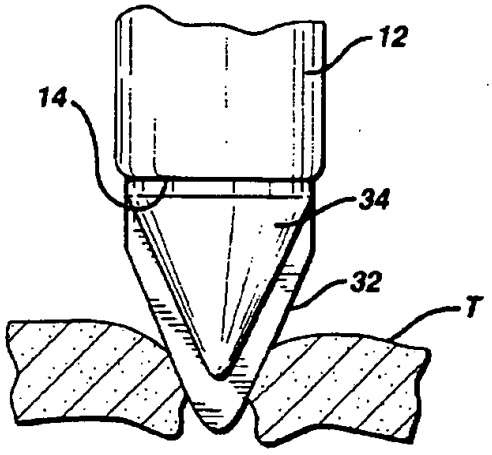


FIG. 5

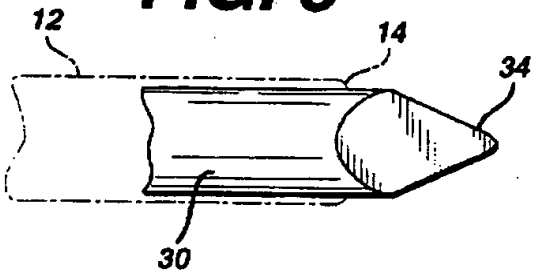


FIG. 6a

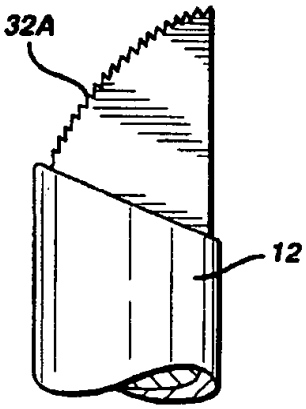
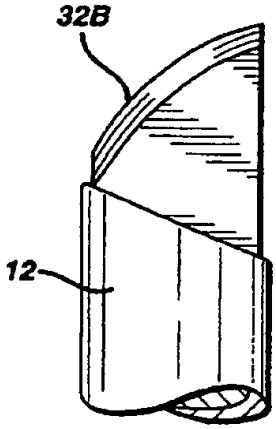


FIG. 6b



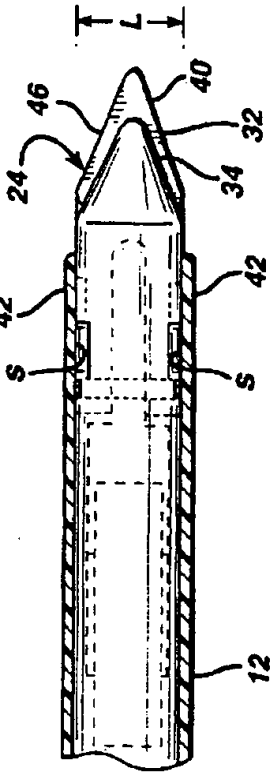


FIG. 7b

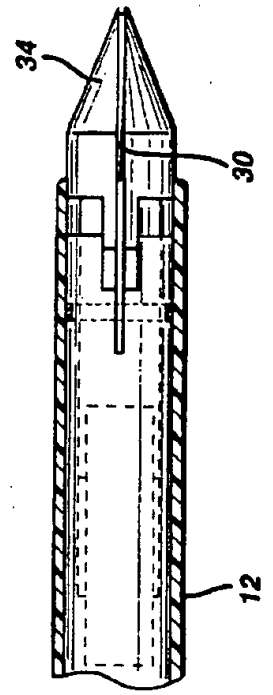


FIG. 7a

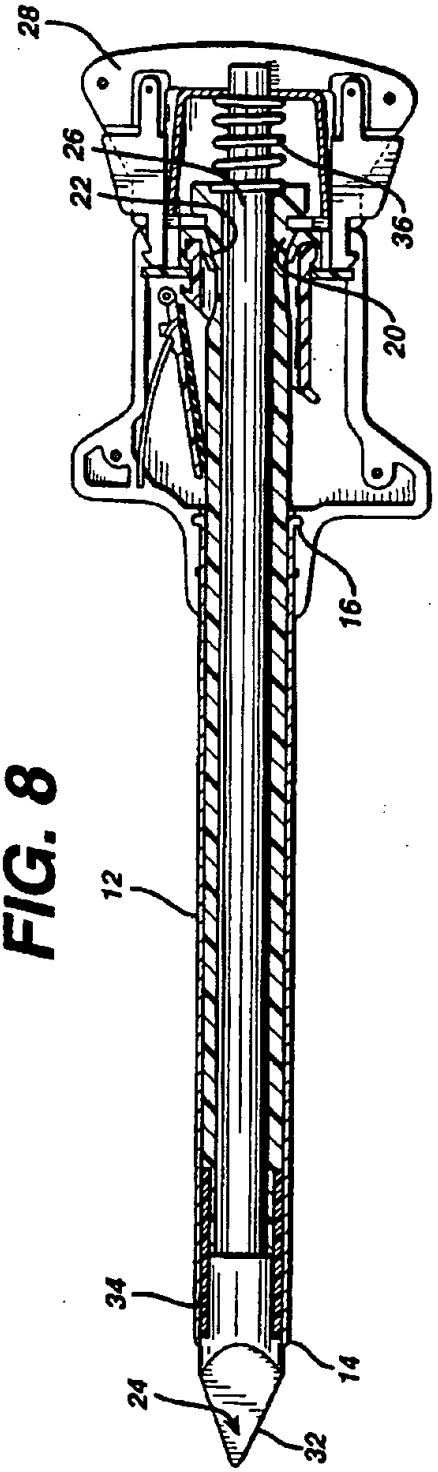


FIG. 8

FIG. 9

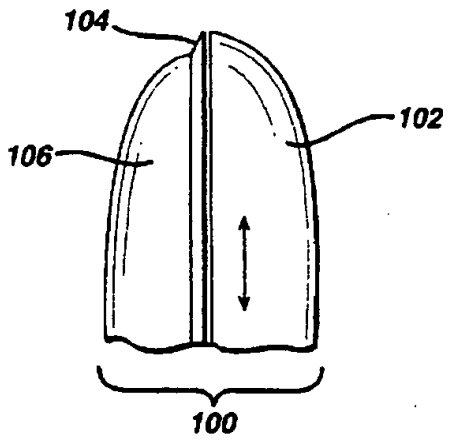


FIG. 9A

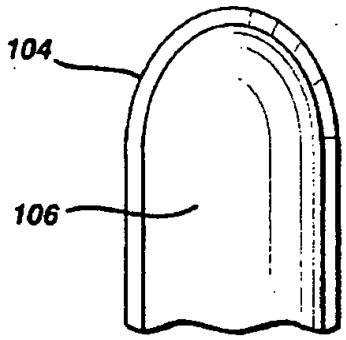


FIG. 10

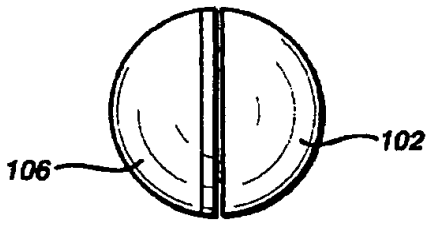
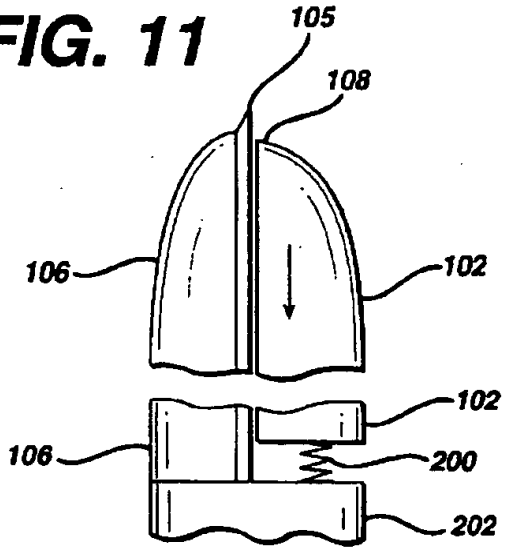


FIG. 11



SAFETY TROCAR

This is a continuation of application Ser. No. 08/296,217, filed Aug. 25, 1994 now abandoned.

FIELD OF THE INVENTION

This invention relates to trocars used to puncture tissue for the performance of laparoscopic or arthroscopic surgery and, in particular, to such trocars which employ a safety device to shield the obturator point immediately after the point has perforated tissue.

BACKGROUND OF THE INVENTION

A trocar generally comprises two major components, a trocar tube and an obturator. The trocar tube or cannula is inserted through the skin. Access is gained through to a body cavity so that laparoscopic or arthroscopic surgery may be performed. In order to penetrate the skin, the distal end of the trocar tube is placed against the skin and an obturator is inserted through the tube. By pressing against the proximal end of the obturator the point of the obturator is forced through the skin until the obturator enters the body cavity. At this time, the trocar tube is inserted through the perforation made by the obturator and the obturator is withdrawn, leaving the trocar tube as an accessway to the body cavity.

It has been found that often a great deal of force is required to cause the obturator point to penetrate the skin and underlying tissue. When the point finally breaks through this tissue, resistance to penetration is suddenly removed, and the obturator point can suddenly reach to penetrate internal organs of the body, which may cause lacerations and other injury to the internal organs. To avert this danger to the patient, trocars have been developed which carry a spring-loaded tubular shield within the trocar tube and surrounding the obturator. The distal end of the shield presses against the skin as the obturator point penetrates the body, until the obturator has formed a perforation with a diameter sufficient to allow the safety shield to pass through. At that time the resistance of the tissue to the spring-loaded shield is removed, and the shield will spring forward to extend into the body cavity, surrounding the point of the obturator. The shield thus protects the internal body organs from inadvertent contact with the point of the obturator. A trocar including such a safety shield is described in U.S. Pat. No. 4,535,773, for example.

The tubular shield in such a trocar will, however, require the incision formed by the obturator to extend to a considerable diameter before the resistance of the tissue pressure has been sufficiently decreased to allow the safety shield to spring forward. It is only when the incision attains the diameter of the shield that the shield is fully able to spring into the body cavity. When the obturator employs a long, tapered cutting tip, this tip must extend a significant distance into the body before the incision is sufficiently enlarged to release the safety shield. It would therefore be desirable to provide a safety shield which will spring forward to shield the obturator tip as soon as possible after entry is gained to the body cavity.

In accordance with the principles of Deniega, U.S. Pat. No. 5,066,288, a safety shield for a trocar obturator is provided which exhibits a rounded, bullet-shaped distal end. A slot is formed in this distal end which corresponds to the geometry of the obturator tip, through which the tip extends during perforation of the skin. With this distal end conforming to the geometry of the tip, a smooth transition is provided from the tip to the distal end of the shield, enabling the shield

to closely follow the obturator tip through the tissue. The rounded distal end will press against the skin and tissue in close proximity to the periphery of the incision as it is formed, and will aid in the enlargement of the incision to enable the shield to spring forward nearly as soon as entry is gained into the body cavity.

One desirable function of such a trocar is for the obturator to slide smoothly within the trocar tube during both insertion and retraction of the obturator. Opposing this need is the necessity to form the obturator to be nearly the same diameter as the tube, so that the tissue perforation will be the size of the tube. Thus, tolerances are generally tight between the diameter of the obturator and the inside diameter of the trocar tube. A further complication is provided by the valve at the proximal end of the trocar tube, which is needed to seal the proximal end during removal of the obturator when the trocar tube and body cavity are insufflated with gases. The valve, which generally takes the form of a hinged flap or trumpet valve, is spring-loaded to bear against the obturator, thereby assuring that the valve will close automatically upon withdrawal of the obturator from the trocar tube. As the valve bears against the obturator it will frictionally disrupt the entry and withdrawal of the obturator. As a result of these tolerance problems, heretofore there has not been an obturator which corresponds identically to the shaft of the trocar cannula, and wider than the inner dimension of the safety shield in which the obturator slides.

Further patient safety would be provided by preventing the sudden extension of the obturator into the body cavity as the obturator tip fully penetrates the tissue. In accordance with yet another aspect of Deniega '688, means are provided which permit only incremental advancement of the obturator as tissue penetration proceeds. Such incremental advancement is provided by a ratchet or screw mechanism, for instance. Yet, this has not alleviated the problem of having an obturator tip with only minimal exposure past the edge of the safety shield at all positions of the safety shield distal end.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a trocar with a safety shield such that the cutting edge of the obturator tip of the safety shield corresponds with the inner diameter of the trocar cannula. This improvement would reduce the force to penetrate the abdominal wall with using such trocar.

It is further desirable to form the obturator tip out of any one of the amorphous-type metals which have currently come into use. These amorphous metals such as amorphous steels and the like, have heretofore not been used in the medical industry for tissue piercing purposes, such as in trocar obturator tips.

Further, it is an object of the invention to provide a safety shielded trocar with a conical shape shield. This type of shield provides for ease of tissues spreading, and as well as adapts to be conformable to various types of obturator tips.

In this type of safety shield it is desired to provide a diametral slot. This slot allows passage of the knife edge which causes a diametral slit to be made in the abdominal wall upon puncture. It is believed that such a slit, would tend to improve healing and simulates the cut of a scalpel, rather than the standard triangular point openings as made with standard trocars. It has the added effect of quicker safety shield response time, to cover the obturator tip.

Furthermore, it has been found that trocar obturators with small diameter (5 mm or less), which are merely two sided

blades, need an increased mass to better puncture the abdominal wall. It is an object of the invention to provide such mass to the trocar obturator.

These and other objects of the invention are provided in a trocar which comprises an obturator connected to an obturator handle and the obturator having a sharpened tip. This obturator may be inserted into a cannula which is connected to a cannula handle. The cannula itself has an opening with an internal diameter. Also, the device contains a safety shield which is spring-loaded within the obturator handle. The safety shield is capable of covering the obturator tip. The safety shield contains within it an opening through which the obturator tip may pass. Generally, the obturator tip when it extends through the opening abuts the inner diameter of the cannula. Generally, the obturator tip is formed from an amorphous metal and contains a curved profile, forming a knife edge. The knife edge indeed may contain serrations. Also, the safety shield is conical in shape so that it is more readily able to spread tissue and has a slit which has a width extending across the inner diameter of the cannula. In one embodiment the blade is connected to a portion of the safety shield.

In operation, therefore the trocar of the present invention affords easier puncture, more rapid healing, and uses highly accurately shaped metals which allow for the rapid piercing of the abdominal wall. The trocar of this invention is able to be pressed through tissue, and yet will be protected by the covering by the safety shield over the obturator tip. The safety shield attached to the bilateral blade provides the ideal means to puncture tissue. Especially true for smaller size trocars (5 mm or less), the obturators are now made much more readily useful.

It is believed that this invention will be better understood by reference to the attached drawings taken in connection with the Detailed Description of the Invention.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a trocar with a conically shaped safety shield;

FIG. **2** is a bottom view of the trocar of FIG. **1**;

FIG. **3** demonstrates the capability of prior art obturator tips as to piercing tissue;

FIG. **4** illustrates the obturator tip of the present invention piercing tissue;

FIG. **5** is a side view of the obturator tip of the invention taken alone without the safety shield covering it;

FIGS. **6***a* and **6***b* are alternate views of an obturator tip of this invention;

FIG. **7***a* is a combination view of the obturator tip of FIG. **5** covered by the safety shield, while FIG. **7***b* is a view of the safety shield allowing the exposure of the obturator tip of the invention;

FIG. **8** is a cross-sectional view of the trocar of FIG. **1**;

FIGS. **9** and **9A** are perspective views of a modified combination blade and safety shield;

FIG. **10** is a top view of FIG. **9**; and

FIG. **11** is a view of FIG. **9** in the cutting position.

DETAILED DESCRIPTION OF THE INVENTION

A safety trocar constructed in accordance with the principles of the present invention is shown in FIGS. **1** and **8**. The trocar **10** includes a trocar tube or cannula **12** having an open distal end **14** and open flanged proximal end **16**. The proximal end **16** is mounted in a trocar handle **18**. There is an aperture **20** at the proximal end **16** of the trocar handle **18** which is surrounded by a gasket ring **22**.

An obturator **24** is slidably and removably located within the trocar cannula **12** and is inserted into the handle **18** and trocar cannula **12** by way of the aperture **20** in the trocar cannula handle **18**. Obturator **24** may reciprocate into obturator handle **28** in a slidable fashion, or conversely may rotate within handle **28**. At obturator proximal end **26** is an obturator handle **28**, and the distal end **30** of the obturator **24** is sharpened as a knife edge **32**. The safety trocar **10** of the FIGS. **1** and **8** is used to puncture a hole in soft tissue by placing the distal end **14** of the trocar cannula **12** against tissue and pressing against the obturator handle **28**. As pressure is exerted against the obturator handle **28**, the safety shield **34** begins to compress the spring **36** inside the obturator handle **28**, and the shield **34** retracts into the handle **28**. This retraction exposes the obturator knife edge **32**, which punctures the tissue.

FIG. **7***b* shows the shield **34** is fully compressed (within the obturator handle **28**) and the obturator knife edge **32** is fully exposed beyond the distal end of the safety shield **34** and trocar cannula **12**. When the obturator knife edge **32** breaks through the inner surface of the tissue, the spring-loaded safety shield **34** springs forward around the obturator distal end **30**, shielding the obturator knife edge **32**, to prevent inadvertent contact of the edge **32** with internal organs of the body inside the tissue being punctured.

Operation of the trocar with the safety shield of this invention is shown in FIGS. **1**, **2** and **7***b*. FIG. **1** is a perspective view of the trocar **10** with the trocar cannula **12** held with inside trocar handle **18** so that the end of the safety shield **34** extends from the distal end **14** of the trocar cannula **12**. An end view of the distal end **12** of the cannula is shown in FIG. **2**. FIG. **5** is a view of the obturator **24** alone without the shield **34** over it. FIG. **7***b* is view of the distal end of the instrument of FIG. **1**, with the knife edge **32** of the obturator **24** extended and the obturator distal end **30** moved apart from the safety shield **34**. In FIG. **7***a*, the obturator distal end **30** is shown covered by the safety shield **34** of FIG. **7***b*.

While this invention has been described in general, various aspects of the device will now be described more in particular. First, it is necessary to look at the obturator distal end **30** as seen in FIGS. **1**, **5**, **7***a* and **7***b*, and **8**. This obturator distal end **30** is generally a diametrally shaped knife edge **32**. It contains two planar faces **40** which form the sharpened knife edge **32**. The diametrally shaped knife edge **32** extends across the entire length L of the inner diameter of the trocar cannula. In this way, the dimensions of the knife edge **32** enable it to be placed flush against the sides S of the trocar cannula **12**. This configuration lowers the force necessary to puncture and penetrate tissue. This is true because with such a knife edge **32**, the obturator **24** is able to move adjacent the edges **42** of the trocar cannula **12**. Therefore, when the tissue T encounters the trocar cannula **12**, there is no further spreading of tissue by the cannula **12**. This is in contrast with the trocar of the prior art inventions, (as seen in FIG. **3**) tissue cannot be caught between the obturator tip and the safety shield.

It should be noted that knife edge **32** should be taken in conjunction with the safety shield **34** of this invention. It will be noticed that the safety shield **34** is conical in shape. This conically-shaped safety shield, generally made of a plastic, will cause the tissue to spread in a very gradual fashion. Of course, the conical shape may be steeper or shallower with respect to the diameter of cannula **12** dependent on the

desired severity of puncture. Naturally, a steeper (longer) conical height will provide smoother puncture. In addition, because the safety shield **34** also abuts the internal diameter of the trocar cannula **12**, the safety shield **34** also is able to perform better spreading of the tissue.

It will be seen that the knife edge **32** at its bottom as in FIG. **2** forms a rather long diametral slits. This is different than the traditional triangular shaped cuts made by traditional trocars. This cut is more like the cut of scalpel. In this way, tissue healing will be promoted in that less tissue must be brought together at the skin surface. Also, because the tissue is very readily pierced, this formulation of the knife edge **32** and safety shield **36** enables easier force to pierce during piercing.

As seen in FIGS. **6***a* and **6***b*, there are shaped two alternate forms of knife edges, **32A**, **32B**, both based on a dimetral slit design. In one knife edge **32A** contains a serrated edge. This serrated edge **32A** is able to cut through tissue with a much greater ease. Of course, the serrated edge **32A** creates greater surface area contact in tissue, but does not detract from the size or shape of the knife edge.

Alternately, in FIG. **6***b*, there is described a tip **32B** with a generally scalpel shape. This scalpel shape used in conjunction with a safety shield compatible with it allows the user to pierce the tissue using the same holding position as using a scalpel. This can be particularly useful for endoscopic applications of such a knife edge **32B**. These knife edges may be placed at an angular orientation to form a cutting shape between 10° and 60° with the sides of the cannula **12**.

In fact, the obturator **24** of this invention is also useful as a piercing instrument. That is, because the obturator **24** of the present design is useful to pierce tissue, much like a scalpel, this obturator **24** may be borrowed to be used endoscopically down a long trocar cannula in order to cut tissue internally. Of course, the safety shield **34** of this mechanism must be adapted so that it is able to be covered only when desired and not automatically after piercing through tissue.

The obturator **32** of this invention maybe formed from an amorphous metal, much like that described in Ser. No. 786,752, now U.S. Pat. No. 5,314,417 assigned to a common assignee as this invention. This amorphous metal can be very highly shaped and refined to very small dimensions, such as about 0.001" or less. In this way, the knife edge of this mechanism is very readily adapted to pierced tissue. Also, because the amorphous metals may be formed as serrated edges as in FIG. **6***a*, we are able to use such a knife edge to perform useful endoscopic functions. Nonetheless, other materials are also available, such as ceramics and the typical stainless steel, from which to form the knife edge.

A modified combination safety shield and blade is described in FIGS. **9**, **10** and **11**. As seen in the figures, attached to the distal end of the obturator shaft **202** which is inserted into the trocar cannula (identified as item **12** in FIG. **1**) is a stationary safety shield **106** and a spring-loaded shield portion **102**. At the distal end of the shield **106** is a sharpened stainless steel semicircular cutting blade **104** similar to the cutting blades shown in FIGS. **1** to **8**. The stationary safety shield and blade combination (as seen in FIG. **10**) encompasses half of the trocar cannula **12** cross-section such that the blade **104** extends diametrically along the circumference of the trocar cannula **12**. Opposite to the stationary portion of the safety shield **106** is the spring loaded shield portion **102**. The proximal end of the spring-loaded shield portion **102** is connected to the distal end of shaft **202** by a spring **200**. The distal end **108** of this movable portion **102** extends to the tip of the blade **104** on the stationary portion **106**. Thus, when this movable portion **106** is in its distalmost position, and locked thereto, by known conventional locking means (also not shown), the blade **104** is protected from cutting tissue. On the other hand, when the movable shield portion is unlocked, the shield **102** is able to retract proximally into the cannula. In this fashion, the blade **104** becomes exposed and blade tip **105** is free to cut tissue. When pressure against the movable safety shield portion **102** is removed, the movable shield **102** returns to its fully extended position and locks in that position. At that point, the blade no longer may cut tissue.

This embodiment is particularly suited for small (5 mm or less) trocars, as the blade **104**, which is quite thin (less than 0.005"), is reinforced by the stationary shield **106**. This mass added to blade **104** provides a useful platform on which to cut tissue.

This new trocar presents many improved uses. There are also equivalents that can be discerned from the description of this invention. Such equivalents are intended to be covered by the scope of this invention as to be derived from the attached claims.

What is claimed is:

1. A trocar obturator comprising:

an elongated shaft having a distal end and a proximal end;

a blade with a distal cutting end and a proximal end, said blade proximal end attached to the distal end of said shaft;

a stationary shield portion affixed to said blade, said stationary shield portion having a distal end and a proximal end;

a movable shield portion attached by a spring to the distal end of said shaft, said movable shield portion slidable with respect to said stationary shield portion and said blade, such that said movable shield portion may be retracted proximally from the distal cutting end of said blade to allow cutting by said blade;

wherein said blade distal cutting end extends distally from said stationary shield distal end, and said blade distal cutting end is generally semicircular in shape.

2. The obturator of claim 1 wherein said trocar obturator is part of a trocar system comprising at least a cannula into which said obturator is insertable.

3. The obturator of claim 2 wherein said cannula is 5 mm or less in diameter.

4. A trocar obturator comprising:

an elongated shaft having a distal end and a proximal end;

a blade with a distal cutting end and a proximal end, said blade proximal end attached to the distal end of said shaft;

a stationary shield portion affixed to said blade, said stationary shield portion having a distal end and a proximal end;

a movable shield portion attached by a spring to the distal end of said shaft, said movable shield portion slidable with respect to said stationary shield portion and said blade, such that said movable shield portion may be retracted proximally from the distal cutting end of said blade to allow cutting by said blade;

wherein said blade distal cutting end extends distally from said stationary shield distal end, and said blade distal cutting end is generally semicircular in shape; and

further comprising locking means to lock said movable shield portion in a locked position with respect to said stationary shield portion and said blade so that the respective distal ends of said movable shield portion and said blade are coextensive in said locked position.

* * * * *

US005545150A

United States Patent [19]

Danks et al.

[11] Patent Number: 5,545,150

[45] Date of Patent: Aug. 13, 1996

[54] **TROCAR**

[75] Inventors: **John K. Danks**, Boca Raton, Fla.; **Richard V. Mazzola**, Bloomfield, N.J.; **Thomas R. Johnson**, Milford, N.H.

[73] Assignee: **Endoscopic Concepts, Inc.**, Delray Beach, Fla.

[21] Appl. No.: **238,959**

[22] Filed: **May 6, 1994**

[51] **Int. Cl.**[6] **A61M 5/00**; A61M 5/14

[52] **U.S. Cl.** **604/256**; 604/265; 604/169; 604/167

[58] **Field of Search** 604/265, 264, 604/256, 263, 272, 51, 169, 167, 172, 280, 164, 158, 244–246; 137/527.6; 251/149.1, 149.2

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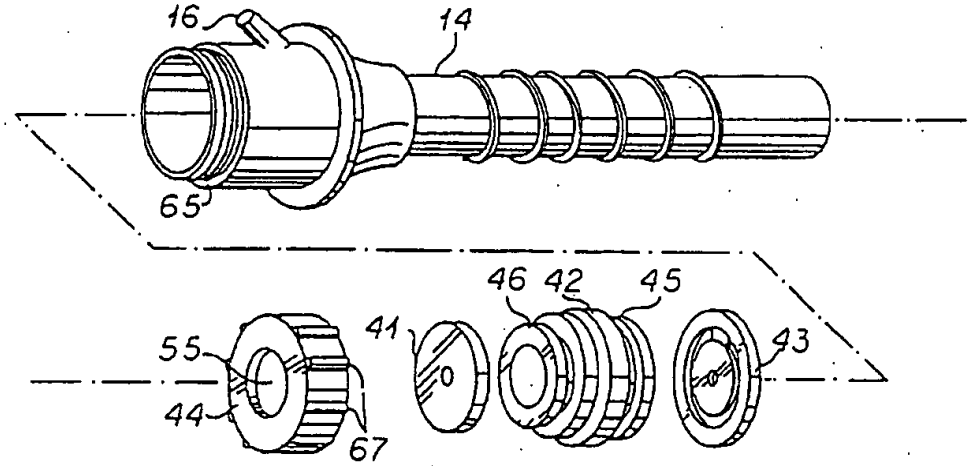
Primary Examiner—John D. Yasko
Assistant Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Miller & Martin

[57] **ABSTRACT**

A trocar is formed from a cannula and an interfitting obturator for penetrating body cavity walls in laparoscopic and endoscopic surgery. The obturator is provided with an improved piercing tip having a pointed blade and an improved double locking blunt nosed shield design. Hydrophilic coatings or components are also employed on the shield and cannula to facilitate quicker shield action covering the pointed blade and ease of entry of the cannula tube through the body cavity wall. The cannula also has an improved inexpensive flexible flapper valve and can be manufactured with a reusable cannula tube but disposable flapper valve assembly to minimize cost.

14 Claims, 5 Drawing Sheets



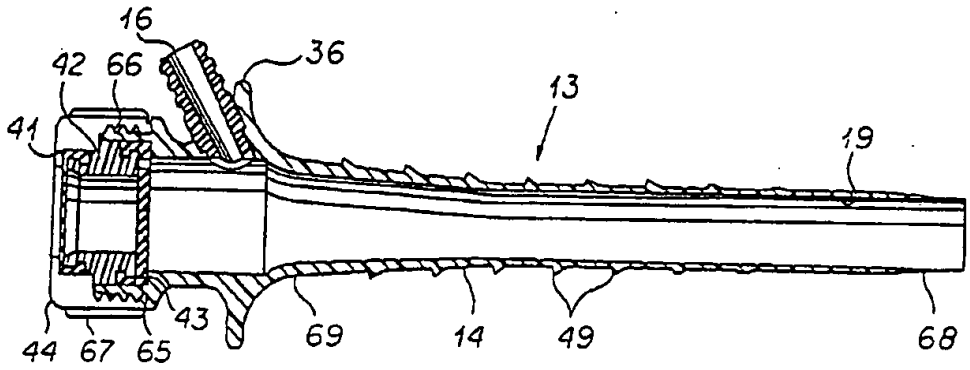


FIG 1A

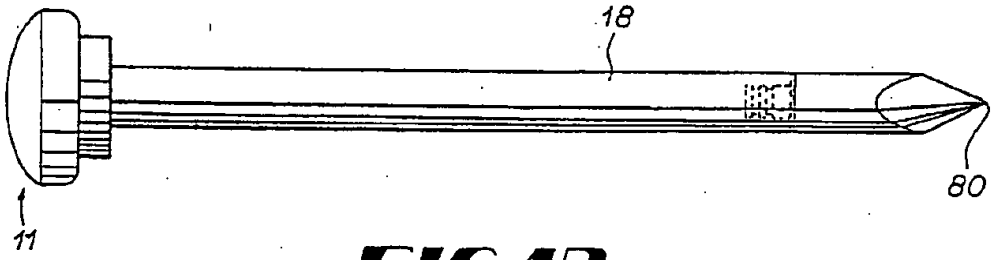


FIG 1B

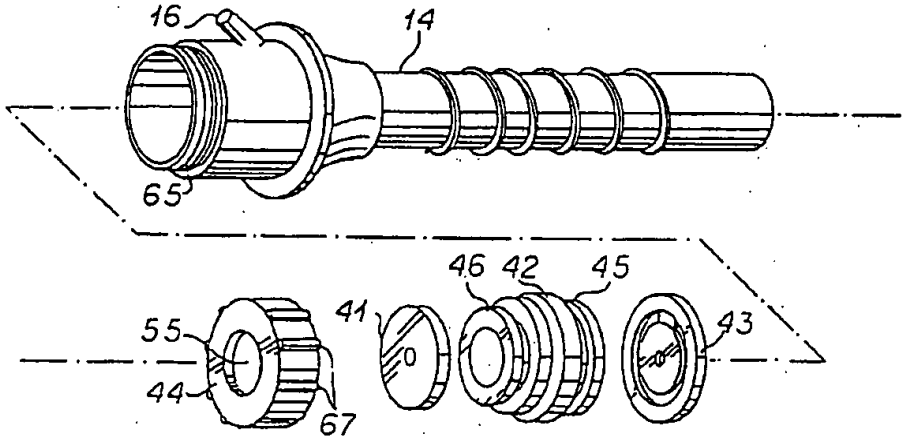


FIG 2

FIG 3A

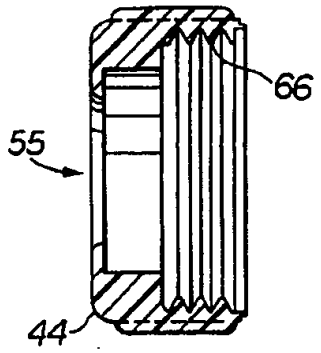


FIG 3B

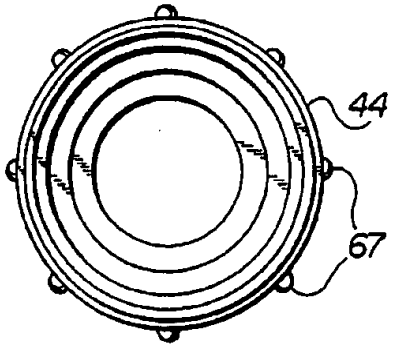


FIG 4A

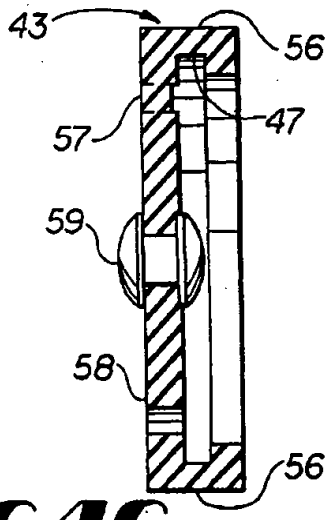


FIG 4B

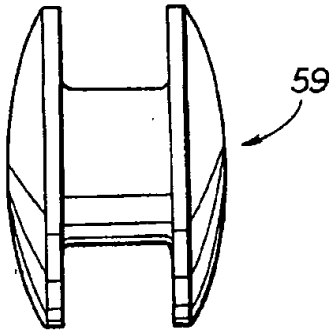


FIG 4C

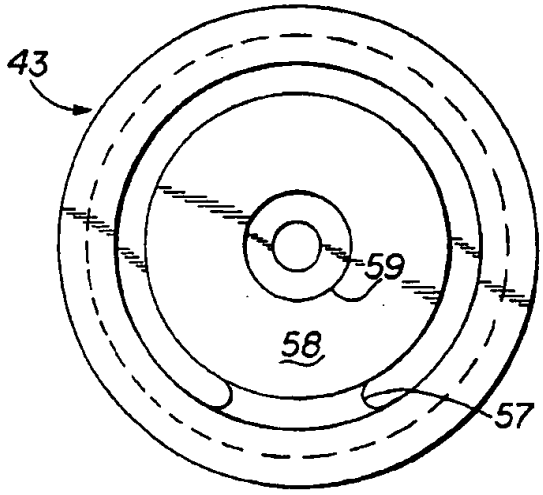
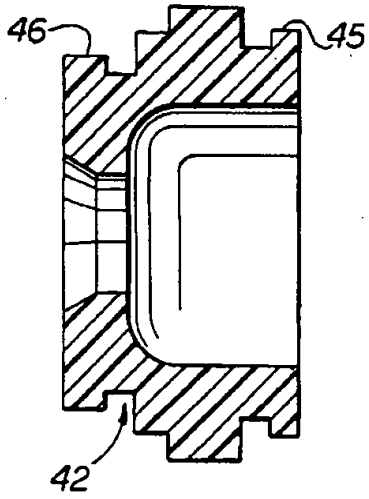


FIG 5



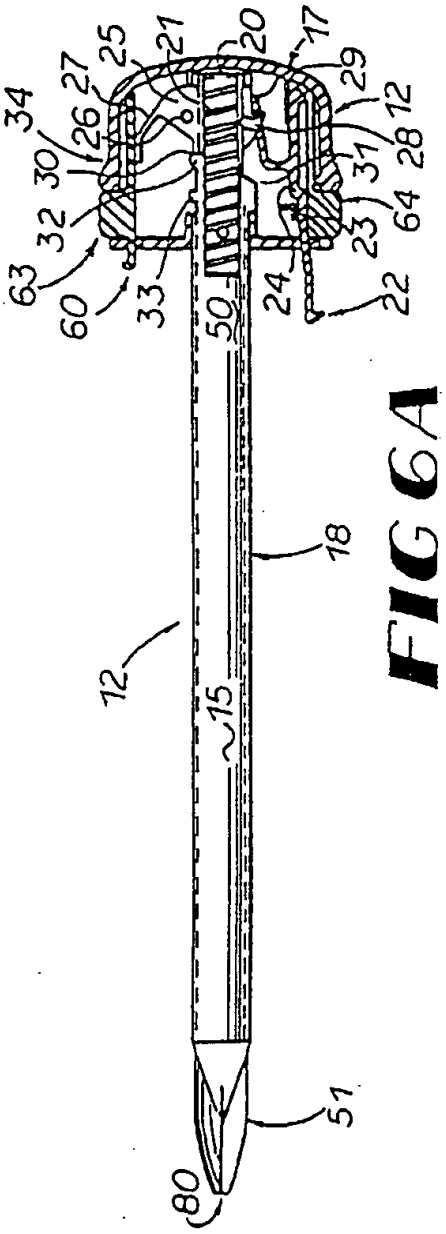

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FIG 6A

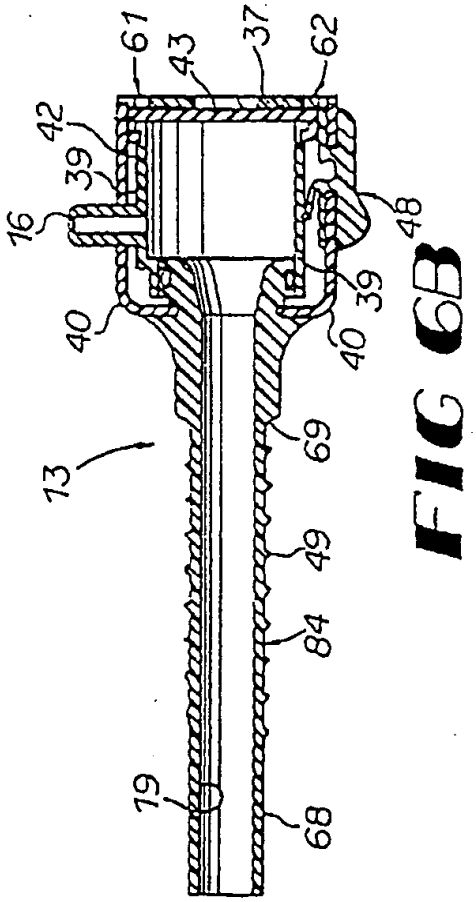
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FIG 6B

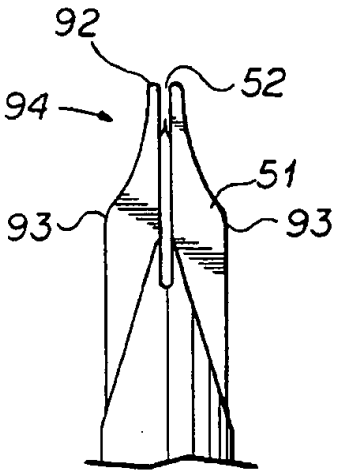

FIG 7A

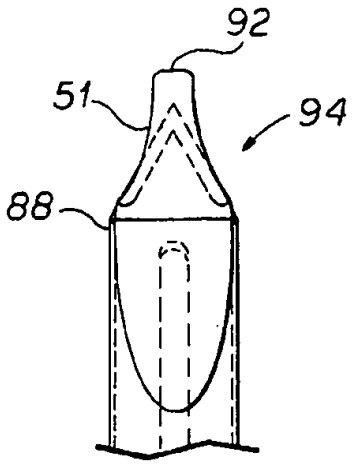

FIG 7B

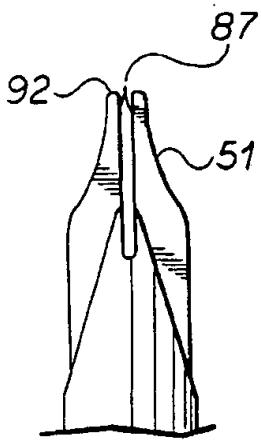

FIG 8A

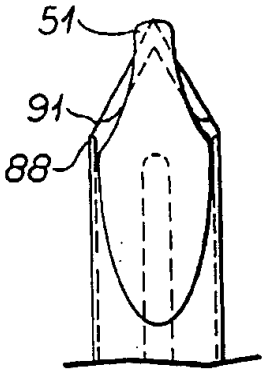

FIG 8B

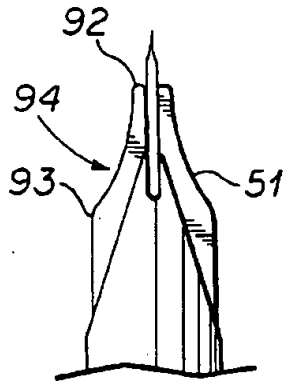

FIG 9A

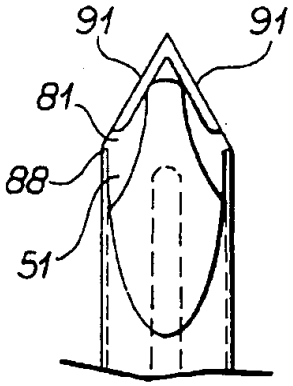

FIG 9B

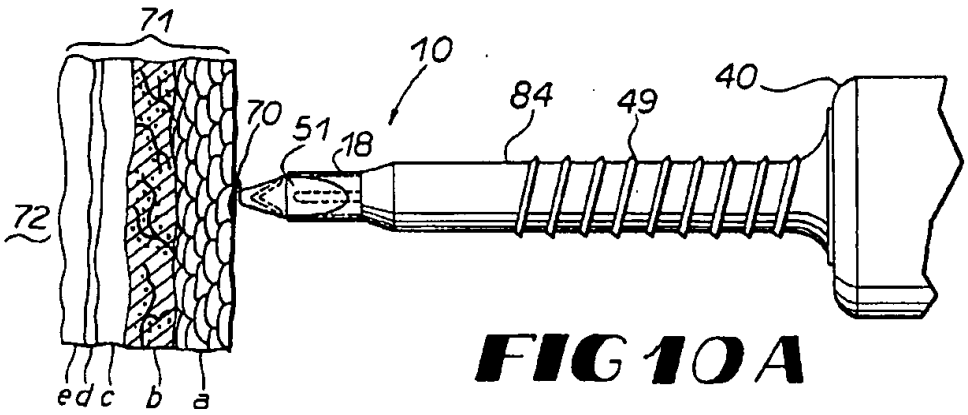

FIG 10A

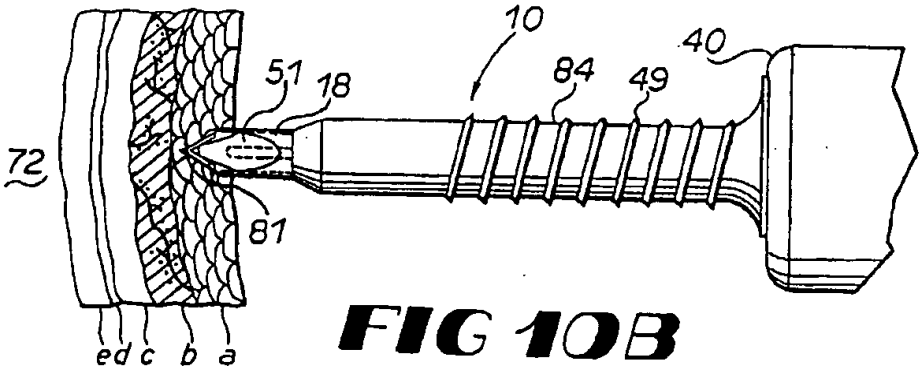

FIG 10B

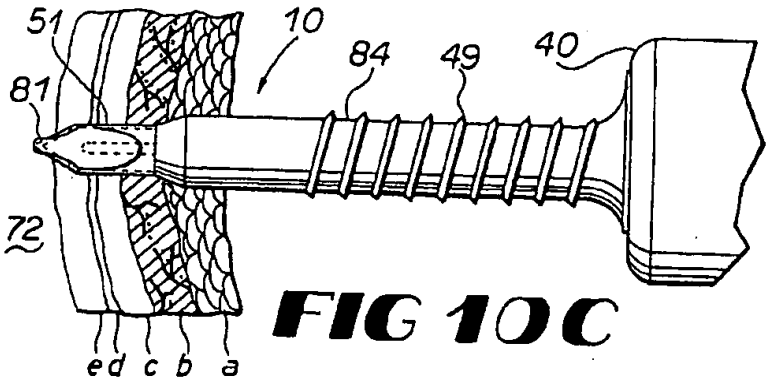

FIG 10C

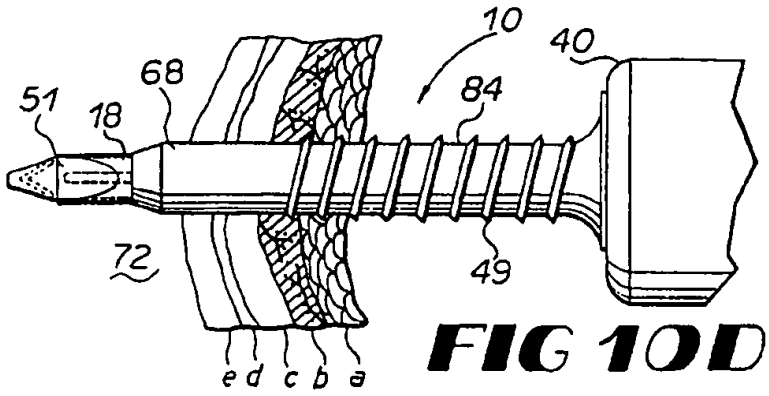

FIG 10D

TROCAR

BACKGROUND OF THE INVENTION

The present invention relates to a surgical instrument commonly referred to as a trocar, or an obturator and cannula, often used in laparoscopic or arthroscopic surgery. More particularly, the invention relates to new and improved designs for shields, seals, and coatings, and to the use of disposable seal and stopcock assemblies on an otherwise reusable instrument.

Many surgical procedures are now being performed with the use of trocars and cannulas. Originally these devices were used for making a puncture and leaving a tube to drain fluids. As technology and surgical techniques have advanced, it is now possible to insert surgical instruments through the cannulas and perform invasive procedures through openings less than half an inch in diameter. Previously these procedures required incisions of many inches. By minimizing the incision, the stress and loss of blood suffered by patients is reduced and the patients' recovery times are dramatically reduced.

Surgical trocars are most commonly used in laparoscopic surgery. Prior to use of the trocar, the surgeon will usually introduce a Veress needle into the patient's abdominal cavity. The Veress needle has a stylet which permits the introduction of gas into the abdominal cavity. After the Veress needle is properly inserted, it is connected to a gas source and the abdominal cavity is insufflated to an approximate abdominal pressure of 15 mm Hg. By insufflating the abdominal cavity, pneumoperitoneum is created separating the wall of the body cavity from the internal organs.

A trocar is then used to puncture the body cavity. The piercing tip or obturator of the trocar is inserted through the cannula or sheath and the cannula partially enters the body cavity through the incision made by the trocar. The obturator can then be removed from the cannula and an elongated endoscope or camera may be inserted through the cannula to view the body cavity, or surgical instruments may be inserted to perform ligations or other procedures.

A great deal of force is often required to cause the obturator to pierce the wall of the body cavity. When the piercing tip breaks through the cavity wall, resistance to penetration ceases and the tip may reach internal organs or blood vessels, with resultant lacerations and potentially serious injury. The creation of the pneumoperitoneum provides some free space within which the surgeon may stop the penetration of the trocar. To provide further protection, trocars have more recently been developed with spring loaded shields surrounding the piercing tip of the obturator. Once the piercing tip of the obturator has completely pierced the body cavity wall, the resistance of the tissue to the spring loaded shield is reduced and the shield springs forward into the body cavity and covers the piercing tip. The shield thereby protects internal body organs and blood vessels from incidental contact with the piercing tip and resultant injury. Trocars including various safety shield designs are described in Yoon, U.S. Pat. Nos. 4,535,773; Moll, 4,654,030; and Moll, 4,601,710. An improved piercing tip comprised of a pointed blade with an improved safety shield is also the subject of commonly owned pending U.S. Ser. No. 08/038,904.

Once the cannula has been introduced into the opening in the body cavity wall, the pneumoperitoneum may be maintained by introducing gas into the abdominal cavity through the cannula. Various seals and valves have been utilized to

allow abdominal pressure to be maintained in this fashion. Maintaining abdominal pressure is important both to allow working room in the body cavity for instruments introduced through the cannula, and to provide free space for the puncturing of the body cavity wall by one or more additional trocars as may be required for some procedures.

While the existing trocars and cannulas have proven useful, several disadvantages remain. The force required to cause the piercing tip to penetrate a body cavity wall is often so great that some physicians must strain to use the trocar with resulting loss of control over the depth of penetration of the instrument. In addition, the existing shield mechanisms do not spring forward to cover the obturator tip as quickly as possible. The delay in covering the piercing tip exposes the patient to unnecessary risk of internal laceration.

Also, with the current emphasis on cost controls in health care, it is desirable to utilize reusable medical instruments whenever possible. The difficulties of cleansing, disinfecting and otherwise decontaminating used trocars has made this a time consuming or impossible task, especially for shielded trocars. Therefore, a need exists for an improved apparatus for performing laparoscopic and similar surgical procedures.

SUMMARY OF THE INVENTION

Accordingly, it is the primary object of the invention to provide a safer trocar for piercing body cavity walls.

It is also an object of the invention to provide an improved shield design which will provide faster coverage of the obturator's piercing tip.

It is a further object of the invention to provide improved coatings for shields and cannulas which will permit easier penetration of body cavity walls and faster coverage of the obturator's piercing tip.

It is another object of the invention to provide a cannula which may be substantially reused without the need for excessive labor in cleaning and decontamination.

It is still another object of the invention to provide a seal or valve which permits easy insertion of surgical and exploratory instruments through the cannula yet still operates effectively to maintain the pneumoperitoneum in the body cavity.

Accordingly, the present invention provides a cannula with a detachable cap and disposable seal assembly and stopcock. To achieve faster shield protection, the forward or distal end of the shield is bottleshaped and is biased to move forward to cover the obturator's piercing tip when the piercing tip penetrates the body cavity wall. The shield may also be fabricated from or treated with hydrophilic materials so that when it is dipped in sterile water or other wetting solution before use, there is less friction between the shield and the body cavity wall allowing faster coverage of the piercing tip. To achieve easier penetration of body cavity walls by the cannula, the cannula may also be treated with a hydrophilic coating. A novel and inexpensive flexible valve is also provided which facilitates insertion of surgical instruments.

BRIEF DESCRIPTIONS OF THE DRAWINGS

FIG. 1A is a cross sectional side view of an improved cannula according to the invention with a disposable gland retainer and end cap.

FIG. 1B is a side view of a conventional obturator which is adapted for use with the cannula of FIG. 1A.

FIG. 2 is an exploded perspective view of the improved cannula of FIG. 1.

FIG. 3A is a cross sectional side view of the end cap of the improved cannula of FIG. 1 in isolation.

FIG. 3B is an end view of the end cap of the improved cannula of FIG. 1.

FIG. 4A is a cross sectional side view of the flexible flapper valve of the improved cannula of FIG. 1 in isolation.

FIG. 4B is an enlarged side plan view of the button which is mounted in the center of the preferred embodiment of the flexible flapper valve.

FIG. 4C is an end view of the flexible flapper valve of the improved cannula of FIG. 1.

FIG. 5 is a cross sectional side view of the gland retainer of the improved cannula of FIG. 1 shown in isolation.

FIG. 6A is a side view in partial cross section of an obturator with an improved shield design and mechanism according to the present invention.

FIG. 6B is a cross sectional side view of a cannula with a flexible flapper valve for use with the obturator of FIG. 6A.

FIG. 7A illustrates a side view of the improved shield design in its fully extended position covering the pointed blade of the obturator.

FIG. 7B illustrates a top view of the shield of FIG. 7A.

FIG. 8A illustrates a side view of the improved shield design in a partially retracted position exposing only portions of the sharpened edges of the pointed blade of the obturator, but covering the sharp tip of the blade.

FIG. 8B illustrates a top view of the shield of FIG. 8A.

FIG. 9A illustrates a side view of the improved shield design in a fully retracted position exposing the tip and sharpened edges of the pointed blade of the obturator.

FIG. 9B illustrates a top view of the shield of FIG. 9A.

FIGS. 10A through 10D show, in sequential diagrammatic sectional views, an embodiment of the present invention as used to puncture a body cavity wall of a patient.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention commonly known as a trocar is comprised of two major components. These are a cannula **13** such as those illustrated in FIGS. **1A** and **6B**, and an obturator such as the traditional obturator **11** in FIG. **1B** or the shielded obturator **12** illustrated in FIG. **6A**. The obturator **11** of FIG. **1B** and cannula **13** of FIG. **1A** are interfitting and as explained below are used together to penetrate a body cavity wall. Once the body cavity wall is penetrated, however, the obturator **11** may be removed and other medical instruments may be introduced into a lumen **19** of the cannula **13**.

The cannula **13** of FIG. **1A** consists of three components and two seal assemblies. The components are the cannula tube **14**, the gland retainer **42** and the cap **44**. The outer surface of the cannula tube **14** of FIG. **1A** is shown with a helically wound thread **49** preferably beginning at a reduced height a short distance from the distal end **68** of the cannula tube **14** and gradually increasing to its full height as it proceeds toward the proximate end **69**. At the proximate end **69** of the cannula tube **14**, there is a raised flange **36** for convenience in handling the cannula **13**. The proximal end of the cannula above the raised flange **36** forms a handle. Above the flange **36** is a gas port **16** which can be connected to a gas supply, not shown, to supply gas through the lumen **19** of the cannula tube **14** into a body cavity to create or maintain pneumoperitoneum. Above the gas port **16** are male threads **65** which allow the cannula tube **14** to be securely coupled with cap **44** which has corresponding female threads **66**. The cap **44** also has an aperture **55** to permit insertion of an obturator **11**, and gripping protrusions **67** to facilitate fastening and unfastening the cap **44**. Mounted concentrically mostly within the proximate end **69** of the cannula tube **14** and held in place by the cap **44** is the gland retainer **42**. The cap **44** is shown in isolation in FIGS. **3A** and **3B**.

The gland retainer **42** shown in isolation in FIG. **5**, holds two seals, **43** and **41**, in place. Flexible flapper seal **43** shown in FIG. **4A** has an annular outer casing **56** which engages the gland retainer **42**. A raised edge **45** at the distal end of the gland retainer **42** fits within a channel **47** shown in FIG. **4A** formed by the lips of the C shaped edge formed by a lip of the outer casing **56** of flexible flapper seal **43**, shown in FIGS. **1A** and **2**. A second raised edge **46** at the proximate end of the gland retainer **42** fits with a channel formed by a similar C shaped edge of the outer casing of wiper seal **41**. Both the membrane seal **41** and flexible flapper seal **43** are fabricated from materials having sufficient elasticity that the outer casings of the seals **41** and **43** can be stretched over ridges **46** and **45** respectively.

The wiper seal **41** is of conventional design, however, the flexible flapper valve **43** is of novel construction. As shown in FIGS. **4A** and **4C**, a hinge **57** extends inward from the outer casing **56** of the flexible flapper valve **43** and mounted on the hinge is the flapper **58**. In the preferred embodiment a hard plastic or metal button **59** is mounted on or through the flapper. When the piercing tip **80**, shown in FIG. **1A**, of an obturator **11** is inserted through the opening **55** in the cap **44**, and through the wiper seal **41**, the piercing tip contacts the hard button **59** of the flexible flapper valve **43** and begins to deflect the flapper **58** from its normal closed position flush against the distal end of the gland retainer **42**. Because the flapper **58** is preferably molded or stamped in one piece with the hinge **57** and outer casing **56** of an elastomeric material, the piercing tip of the obturator might otherwise penetrate or cut into the flapper **58** which could cause resistance to entry of the obturator or damage the flapper **58** so that it would no longer seal the cannula **13** or gland retainer **42** effectively against loss of air through the opening **55** in the cap **44**. The hard button **59** alleviates these possible problems.

When the obturator **12** or other endoscopic instrument is removed from the cannula **13**, the resiliency of the hinge **57** causes the flapper **58** to move to a partially closed position. The flapper **58** is then firmly closed and sealed by action of the air pressure from the inflated body cavity, such air pressure pushing the flapper **58** against the edges of the distal end of the gland retainer **42** and thereby forming an effective seal against further loss of gas.

In its preferred embodiment, the cannula tube **14** portion is manufactured of a durable material such as stainless steel or titanium alloys, capable of withstanding repeated high temperature cleaning and sterilization, while the gland retainer **42** is made of an inexpensive plastic. The cap **44** may be made of either type of material. The gland retainer **42**, containing the flapper valve and possibly also containing a wiper seal, is difficult to clean and sterilize. However, the gland retainer **42** and seals **41** and **43** are relatively inexpensive to manufacture and can be discarded after each use. The cannula tube **14**, and optionally the cap **44**, are relatively easy to clean and sterilize and need not be discarded. By reusing the cannula tube **14**, and the cap **44** if manufactured of an appropriate material, cost and waste can be minimized. If desired the cap **44** can also be manufactured of inexpen-

sive plastic and discarded with the gland retainer 42 after use.

A shielded obturator 12 is shown in greater detail in FIG. 6A. The shielded obturator 12 in FIG. 6A includes an obturator housing 17 which forms a grip or handle. The shielded obturator 12 also includes a hollow obturator sheath 18, the proximal end of which is mounted to the obturator housing 17. The distal end of the obturator sheath 18 is fitted with a piercing tip 80. Housed within the obturator sheath 18 is the shield 15, shown in its extended position with the distal end 51 covering the piercing tip 80. The proximal end 50 of the shield 15 is received some distance within the hollow obturator sheath 18 where it is outwardly biased by a biasing means such as the coiled spring 21 interposed between the proximal end 50 of the shield 15 and the inner wall 20 of the obturator housing 17.

Still referring to FIG. 6A, a double action latch 34 for locking the shield 15 in both the extended position and a partially retracted position is illustrated. The latch 34 comprises a biasing means such as the spring 27, a blocking member such as the illustrated pivoting chock 25, an actuator such as the trigger 48, shown in FIG. 6B, and a linkage between the actuator and the blocking member such as the linking member 24. The illustrated latch operates to keep the shield 15 locked in the extended position except when armed or actuated. To lock the shield 15, a solid portion 30 of the pivoting chock 25 engages with a first lug 32 on the proximal end 50 of the shield 15 to prevent the shield 15 from retracting further toward the inner wall 20 of the obturator housing 17 and thereby exposing the piercing tip 80.

In order to permit the shield 15 to be retracted, the latch 34 must first be armed or actuated. To accomplish this, the shielded obturator 12 and cannula 13 must first be interfitted. In FIGS. 6A and 6B, the distal end 22 of the linking member 24 from the shielded obturator 12 is received through opening 62 and engaged in the trigger 48 mounted in the cannula 13. Also a guiding tab 60 from the shielded obturator 12 is received in an opening 61 in the cannula 13. By depressing push buttons 63 and 64, the guiding tab 60 and linking member 24 can be disengaged, allowing for easy separation of the shielded obturator 12 from the cannula 13.

To arm the latch 34 in the embodiment illustrated in FIG. 6A, the distal end 22 of the linking member 24 engages with a trigger 48, shown in FIG. 6B. When the trigger 48 is depressed and pushed forward toward the piercing tip 80, the linking member 24 is likewise pulled forward. A hook 29 on the proximate end of the linking member 24 is engaged in a cradle 28 on the pivoting chock 25. As the linking member 24 is pulled forward, it causes the pivoting chock 25 to turn on its pivot 26 and thereby rotates the solid portion 30 away from the lug 32 on the proximal end 50 of the shield 15. This arms or actuates the obturator 12.

As the trigger 48 continues forward, the linking member 24 also travels forward until a stop block 23 halts further movement. When the stop block 23 halts further movement, the linking member 24 is in measured close proximity to a cam 31 protruding from the proximal end 50 of the shield 15. As soon as the surgeon applies pressure to the trocar 10, the proximal end 50 of shield 15 is pushed back into the housing 17. After the shield 15 is pushed back sufficiently that a second lug 33 on the proximal end 50 of the shield 15 has reached the solid portion 30, the cam 31 on the proximal end 50 of the shield 15 then dislodges the hook 29 of the linking member 24 from the cradle 28 of the pivoting chock 25. A biasing means such as the spring 27 acting on the pivoting chock 25 now causes the solid portion 30 of the pivoting chock 25 to try to return to its original locking position. When the shield 15 is fully retracted, the pivoting chock 25 cannot return to a locking position. Yet if the shield 15 should extend even partially, so that it is no longer fully retracted, the solid portion 30 of the pivoting chock 25 can engage the second lug 33, and become locked against the shield again becoming fully retracted. This is referred to as a partially locked or semi-protective position. In this fashion the second lug 33 acts as a detent allowing the shield to rachet forward to an extended position.

If the distal end 51 of the shield 15 and piercing tip 80 are properly designed, the partially locked position can provide substantial protection to the patient. With the pointed blade designs discussed in FIGS. 7–9, it is possible to have the shield cover the sharp tip 87 of the blade and allow only the sharpened edges 91 of the blade to remain exposed as shown in FIG. 8. This allows the sharpened edges 91 to continue cutting the body cavity wall but without risk of exposing the sharp tip 87 thus reducing the chance of inadvertent injury during the incision.

When the entire piercing tip 80 of the obturator 12 has passed through the body cavity wall and there is no resistance to the spring loaded shield the shield 15 will spring completely forward to cover the piercing tip 80, as shown in FIGS. 6A and 7, and the pivoting chock 25 will pivot into its original locking position, where the solid portion 30 of the pivoting chock 25 acts to block rearward movement of the first lug 32 on the proximate end 50 of the shield 15. In this fashion, once the body cavity wall has been pierced by the sharp tip 87 and the shield 15 has partially locked, the shield 15 cannot again retract to expose the sharp tip 87 of the piercing tip 80 unless the operating physician uses the trigger 48 to rearm the trocar 10. Once the piercing tip 80 has completely penetrated the body cavity wall and the shield 15 has fully locked, the shield 15 cannot again retract to oppose any portion of the piercing tip 80.

Referring again to FIG. 6B, the cannula 13 includes an outer housing 40, an inner housing 39, and a cannula tube 84 which is secured to and extends from the inner housing 39. In addition, the inner housing 39 is mounted within the outer housing 40. The inner housing 39 contains a gas sealing means such as the illustrated flexible flapper valve 43. The flexible flapper valve 43 will allow the introduction of the obturator sheath 18 of a shielded obturator 12, or other endoscopic instruments (not illustrated) without substantial loss of gas from the body cavity. As shown in FIG. 6B, when no instrument is inserted, the flapper 43 closes against the end plate 37 to maintain the gaseous pressure in the body cavity.

FIGS. 7–9 illustrate the presently preferred embodiment of the piercing tip 80, which is comprised of a pointed blade 81. The illustrated pointed blade 81 is substantially planar and has a central sharp tip or pointed distal end 87 and straight sharpened edges 91 proceeding from both sides of said distal end 87 to the shoulders 88. In alternative constructions, the blade 81 may have slight convex or concave curve to the sharpened edges 91. The point of the blade may be acute as illustrated or rounded. Other variations of a pointed blade or blades may also be utilized.

As shown in FIGS. 7A and 7B, the distal end 51 of the shield 15 used with the illustrated pointed blade is "bottle shaped" or "dolphin nose shaped" in that it has a blunt end 92 at its most distal point which widens slowly at first and then more rapidly so that there is a slight concavity 94 as the distal end 51 of the shield 15 proceeds from the blunt end 92

to a shoulder **93**. As shown in FIGS. **8**A and **8**B, when the shield end **51** is of this shape, it is possible for the blunt end **92** to cover the pointed distal end **87** of the blade **81** so that no additional penetration is possible, while still leaving portions of the sharpened edges **91** exposed. In this fashion, when the pointed distal end **87** of the blade **81** has penetrated the body cavity wall, but before the blade **81** is entirely through the wall, the blunt end **92** of the shield can move forward and be partially locked while still allowing the sharpened edges **91** of the pointed blade **81** to expand the incision in the body cavity wall so that the obturator and cannula may be introduced to communiate with the body cavity.

FIGS. **10**A through **10**D illustrate the piercing tip **80** and shield end **51** of the trocar **10** formed from the obturator **12** and cannula **13** of FIGS. **6**A and **6**B in use. In FIG. **10**A, a small incision **70** is made in the surface of the skin or epidermis "a" of the body cavity wall **71** of a patient. The piercing tip **80**, in this case the pointed blade **81**, of the trocar **10** with extended shield **15** may then be placed against the incision **70** as shown. When the trocar **10** is in this position, it may be armed or actuated by depressing the trigger **48** (shown in FIGS. **6**A and **6**B) and sliding the trigger **48** forward as explained above. When manual force is applied to the obturator housing **17** which forms the trocar handle (shown in FIG. **6**A) pushing the trocar to the left, the resistance of the body cavity wall **71** holds back the distal end **51** of the shield **15** and the pointed blade **81** is exposed as shown in FIG. **10**B. The pointed blade **81** then slices through the dermis "a" and subcutaneous tissue including fat cells, muscle, and facia, depicted as "b," "c," "d" and "e" in FIGS. **10**A–**10**D. The various layers of the body cavity wall **71** vary depending upon the cavity being pierced, but in general, the layers of facia are particularly resistant to penetration.

In FIG. **10**C, immediately after the sharpened tip **87** of the pointed blade **81** has penetrated the innermost layer "e" of the body cavity wall **71**, the blunt end **92** of the distal end **51** of the shield **15** is forced forward through the incision **70** by the bias of the coil spring **21**. When the shield **15** reaches this partially retracted position and the preferred double action latch **34** of the obturator **12** illustrated in FIG. **6**A is used, the shield **15** will lock so that it cannot be retracted to again expose the sharp tip **87** of the pointed blade **81**, yet the shield **15** permits the sharp edges **91** of the blade **81** to continue cutting. This is a semi-protected shield position. In this partially locked or semi-protected position the interior of the body cavity **72** and organs, blood vessels and other anatomical structures are protected against puncture by the sharp end **87** of the blade **81**.

FIG. **10**D shows that the shield end **51**, the obturator sheath **18**, and the distal end **68** of the cannula tube **84** all proceed through the incision **70** in the body cavity wall **71** as manual force continues to be applied to the trocar **10**. Just as the shoulder **93** of the distal end **51** of the shield **15** passes through the inner layer "e" of the body cavity wall **71**, the resistance of the body cavity wall **71** is significantly reduced and the shield **15** is pushed to its fully extended position with the distal end **51** covering the pointed blade **81**. This action completely protects the interior of the body cavity **72** immediately after the full penetration of the pointed blade **81** through the body cavity wall **71** and protects organs, blood vessels and other anatomical structures from incidental contact even with the sharpened edges **91** of the blade **81**. Simultaneously with the full extension of the shield **15** into its protective position covering the pointed blade **81**, the pivoting chock **25** engages the first lug **32** on the proximate end **50** of the shield **15**, which prevents the shield **15** from being retracted to expose the pointed blade **81** until the trocar **10** is again actuated by depressing and moving the trigger **48** forward.

In order to improve the performance of the shield **15** in moving forward through the body cavity wall, it is possible to either mold the shield **15** or shield end **51** from a hydrophilic plastic or to coat the shield with a hydrophilic coating. By providing the shield end **51** with appropriate hydrophilic properties, the shield end **51** can be dipped in a wetting solution, usually of water or an appropriate alcohol solution, and the shield end **51** will then have a lower coefficient of friction and will more easily slide through the incision **70** in the body cavity wall **71** to cover the piercing tip **80**. Appropriate coatings or compounds must be substantially nonreactive with respect to living tissue and non-thrombogenic when in contact with blood. Appropriate hydrophilic coatings would include polyvinylpyrrolidone-polyurethane or polyvinybutyrol interpolymers as described in U.S. Pat. Nos. 4,100,309 and 4,119,094. Appropriate molding compounds, which could alternatively also be applied as coatings, include hydrophilic polymer blends with thermoplastic polyurethane or polyvinylbutyrol and hydrophilic polyvinylpyrrolidone or other poly(N-vinyl lactans) as described in U.S. Pat. Nos. 4,642,267 and 4,847,324. An appropriate hydrophillic coating will reduce the coefficient of friction for stainless steel by over 60% and can reduce the coefficients of friction for plastics by over 90%. This permits hydrophillic plastics to be used for the shield **15** rather than steel.

The same hydrophilic coatings or compounds may also be used in the cannula **13** which will facilitate the entry of the distal end **68** of the cannula **13** into the incision made by the obturator **12**. Although the sharpened blade **81** does not provide substantial resistance, some minor improvement might also be achieved by applying a hydrophillic coating to this blade **81**.

Numerous alterations of the structures herein described will suggest themselves to those skilled in the art. It will be understood that the details and arrangements of the parts that have been described and illustrated in order to explain the nature of the invention are not to be construed as any limitation of the invention. All such alterations which do not depart from the spirit of the invention are intended to be included within the scope of the appended claims.

We claim:

1. A cannula comprising:

(a) a cannula tube with an outer surface and an interior lumen, and having a distal end and a proximate end, said proximate end forming a cannula handle;

(b) a gland retainer fitted adjacent to the proximate end of said cannula tube and substantially within the cannula handle, said gland retainer having a distal end and a proximate end;

(c) a flapper valve mounted on said gland retainer distal end, wherein the flapper valve comprises an outer casing, a hinge, and a flapper and wherein at least the outer casing and the hinge of said flapper valve are integrally fabricated from an elastomeric material; and

(d) a cap releasably fastened to the cannula handle thereby confining said gland retainer.

2. The cannula of claim **1** wherein the outer casing, hinge and flapper of the flapper valve are integrally fabricated from an elastomeric material.

3. The cannula of claim **2** wherein said flapper further comprises a relatively hard surfaced centrally disposed button.

4. The cannula of claim 1 wherein the flapper valve is comprised of an outer casing having two inward facing lips defining a channel,

and wherein the gland retainer distal end has a raised edge which is received within said channel.

5. A cannula comprising:

(a) a cannula tube with an outer surface and an interior lumen, and having a distal end and a proximate end;

(b) a gland retainer fitted partially within the proximate end of said cannula tube, said gland retainer having a distal end and a proximate end;

(c) a flapper valve mounted on said gland retainer distal end, said flapper valve comprising an outer casing, a hinge and a flapper and wherein at least the outer casing and the hinge of said flapper valve are integrally fabricated from an elastomeric material; and

(d) a cap releasably fastened to the proximate end of the gland retainer.

6. The cannula of claim 5 further comprising a wiper seal mounted on said gland retainer proximate end.

7. The cannula of claim 6 wherein the wiper seal is comprised of a membrane and an outer casing, said outer casing having a first raised inward facing lip supporting said membrane and a second raised inward facing lip defining a channel, and wherein said gland retainer has a raised edge which is received within said channel.

8. The cannula of claim 5 wherein the outer casing, hinge and flapper of the flapper valve are integrally fabricated from an elastomeric material.

9. The cannula of claim 8 wherein said flapper further comprises a relatively hard surfaced centrally disposed button.

10. The cannula of claim 5 wherein the flapper valve is comprised of an outer casing having two inward facing lips defining a channel, and wherein the gland retainer has a raised edge which is received within said channel.

11. The cannula of claim 5 wherein the gland retainer interfits concentrically within the cap and the proximate end of the cannula tube.

12. The cannula of claim 5 wherein the distal end of said cannula tube is provided with a hydrophilic coating.

13. The cannula of claim 5 wherein the cannula tube is manufactured from a metal selected from the group of stainless steel and titanium alloys.

14. The cannula of claim 5 wherein the gland retainer is disposable. opposite that shown in FIG. 4A

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